Quality of Life and Treatment Outcome Under Inhalation Sedation

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Submitted in accordance with the requirements for the degree of
Professional Doctorate in Paediatric Dentistry

The University of Leeds

School of Dentistry

September, 2016

The candidate confirms that the work submitted is his/her own and that appropriate credit has been given where reference has been made to the work of others.

DEDICATIONS

To my lovely wife and beautiful daughter.
I love you both.

ACKNOWLEDGEMENTS

This thesis would not have been possible without the help of countless people. First of all I would like to acknowledge my supervisors Dr Tahmassebi and Prof Duggal, without whom, I would have been completely lost in the world of research. Secondly I want to thank Dr Jing Kang for her assistance with the statistics and data analysis. Countless hours were spent sending many emails back and forth and finally I have this thesis to show for. Thirdly, I would like to thank the sedation department with putting up with me jumping in to get the patients recruited. I appreciate your great help in making this research work. I would also like to thank all the postgraduate students who help me by making sure the patients attended their review appointments. Those final pieces of paper made the difference in my thesis.

Lastly, I want to thank my family for encouraging me to pursue a career in paediatric dentistry and helping me along the way. During the course of this research I met my amazing wife and started a family here. I cannot think of a better way to end my training here at Leeds

Thank you all.

ABSTRACT

Title: Quality of life and treatment outcome under inhalation sedation

AIM:

To assess the outcome of treatment and changes in quality of life (QoL) following comprehensive dental treatment using nitrous oxide inhalation sedation.

METHODS

Patients attending the Sedation Unit at the Leeds Dental Institute were asked to participate in the study. Baseline questionnaires included a quality of life (QoL) assessment (COHIP-SF19) and the p-IOSN tool (indication of sedation need). Participants were followed up to evaluate the outcome of their treatment. Those who completed treatment as planned completed a second QoL assessment at least 2 weeks following their last appointment.

RESULTS:

In total, 97 patients were recruited (44 males and 53 females), and of these 47 completed treatment as planned with 31 completing a 2nd QoL assessment, 18 are currently undergoing treatment, and 20 were referred to GA. There was a statistically significant improvement in QoL following treatment (p value= 0.000), with the largest effect size noted in the “oral health well-being” domain. When not controlling for other factors, a change from high to low anxiety was significantly associated with high baseline QoL (B= 6.632 p value = 0.023). Changing from high to low sedation need decreased the likely need for referring to GA and not completing treatment as planned (B -1.788 p value 0.05).

CONCLUSION:

Rendering the child dentally fit improved QoL. Using anxiety, gender, age group or sedation need as measures could not accurately predict the treatment outcome of the child or the baseline QoL scores, when controlling for sedation need and anxiety.

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologists
BDA	British Dental Association
BIIP	Blood injury injection phobia
CFSS-DS	Children's Fear Survey Schedule – Dental subset
CNS	Central Nervous System
COHIP(-SF19)	Child Oral Health Impact Profile (Short Form)
C-OIDP	Child Oral Impact on Daily Performance index
CPQ	Child Perception Questionnaire
DAS	Dental Anxiety Scale
DFSS-SF	Dental Fear Survey Schedule – Short Form
DREC	Dental Research Ethic Committee
EAPD	European Academy of Paediatric Dentistry
ECOHIS	Early Childhood Oral Health Impact Scale
FIS	Facial Image Scale
GA	General Anaesthesia
IACSD	Intercollegiate Advisory Committee for Sedation in Dentistry
IOSN	Indication of Sedation Need
IV	Intravenous
LA	Local anaesthetics

LDI	Leeds Dental Institute
MCDAS	Modified Child Dental Anxiety Scale
$MCDAS_f$	Faces version of the Modified Child Dental Anxiety Scale
MDAS	Modified Dental Anxiety Scale
Min	Minutes
Mg	Milligram
mg/kg	Milligram per kilogram
MOHRQoL	Michigan Oral health Related Quality of Life
NICE	National Institute of Health and Care Excellence
OHRQoL	Oral Health Related Quality of Life
OR	Odds Ratio
p-IOSN	Paediatric version of the Indicator of Sedation Need
PSI	Palmar sweat index
POQL	Paediatric Oral Health Related Quality of Life
QoL	Quality of Life
R&D	Research & Dev elopement
SDCEP	Scottish Dental Clinical Effectiveness Programme
SFP(-R)	Smiley Face Program (-Revised)
SIGN	Scottish Intercollegiate Guidelines Network
SOHO-5	Scale of Oral Health Outcomes for 5 yrs
UK	United Kingdom
VPT	Venham Picture Test

Vs	Versus
yrs	Years

Chapter 1

1.0 LITERATURE REVIEW

Anxiety is defined as 'a feeling of worry, nervousness, or unease about something with an uncertain outcome'. Fear and anxiety are common in the dental setting, affecting 9.4% of children (Carrillo-Díaz et al., 2013a). However, other studies reported it to be as high as 44% for low to moderate fear and 10% for high fear (Taani et al., 2005). Children are not able to express anxiety and fear as effective as adults; this can affect their behaviour during the treatment and the child may be labelled as "unco-operative" (Chadwick, 2002). With the adult patient who suffers from dental anxiety, they were often treated under intravenous sedation (IV) (Davies et at., 2011).

Although the terms "dental anxiety", "dental phobia", and "dental fear" are sometimes used synonymously, they are different entities all together. Dental anxiety is a term that used to describe all types of dental-related fears and phobias. A "phobia" is classified as an anxiety related disorder where the actual fear interferes with the patient's everyday life. Fear, on the other hand, is not as extreme (Porritt et al., 2013). However, Klingberg and Broberg (2007) described dental anxiety as a state of apprehension relating to the dental treatment in which something dreadful is going to happen, coupled with a sense of loss of control. Both anxiety and fear are considered primitive emotions which can be beneficial in maintaining the safety and well-being of healthy individuals; anxiety increases sensitivity to external stimuli, while fear stimulates avoidance behaviour (Sylvers et al., 2011). A diagnosis of "phobia" can only be made when certain criteria are met, based on the Diagnostic and Statistical Manual of Mental Disorders (DSM–IV) published by the American Psychiatric Association (1994):

- Marked and persistent fear on an identifiable situation and/or object

- When exposed to the phobia, an immediate anxiety response is seen (e.g. panic attacks in adults and tantrums, crying, and clinging in children)
- The patient knows that the fear of the object is extreme and irrational. This may be difficult for children.
- The stimulus is either avoided or endured with great apprehension
- The phobia significantly interferes with every-day routine, social-life, or occupation. There is increased grief in having a phobia
- The patient must have had the symptoms for 6 months, if below 18 years of age.
- No presence of other mental disorders

1.1 Anxiety and Fear

1.1.1 Aetiology of fears:

Several theories have been developed to discuss how phobias are acquired; however, many of the previous and current theories do not seem to explain certain critical aspects of phobia development. In order to characterise an object or situation as a phobia, there are several features it must follow. These include a severe reaction evoked by the feared stimulus, the multiple pathways fear is “learnt”, the disproportionate distribution of fears across various probable stimuli, and the differences between individuals in terms of their fear expression in spite of similar experiences. This led to new theories that were proposed or in some cases, old theories were amended (Armfield, 2006).

Armfield (2006) discussed multiple theories of genesis of phobia and their criticism:

1. Classical conditioning theory. This theory states that a phobia is formed when a previously neutral stimulus is paired with an aversive response and hence becomes fear evoking. This may stimulate a motivational drive to avoid the stimulus (Armfield, 2006). However, critics of this theory stated that fear was conditioned and not phobia. Moreover, certain aspects of phobia are not covered. These include the ease of acquisition, the irrationality of phobia, the

uneven distribution of potentially “fear relevant” stimuli, and the resistance to elimination of the phobia (Seligman, 1971).

2. Preparedness model. This theory is based on Seligman (1971) who proposed the 4 discrepancies concerning the classical conditioning theory. The process of fear development, according to this theory, is a “biologically prepared learning”; the fear evoking stimulus is associated with a sense of danger and has been throughout human history. This theory is based on 3 assumptions. The first is that phobias are from the experience of an initially neutral stimulus that is linked to an aversive event. Secondly, the stimuli can be in any stage of preparedness from “prepared” to “contra-prepared”. Finally, the prepared neutral stimulus has some biological significance in order to be fear evoking (spiders and snakes are fear evoking so can be prepared for fear). Critics of the “Preparedness Model” state that survival relevance, a stimuli that is associated with danger, is not the only factor. After controlling for dangerousness and unpredictability, it was found that survival relevance was not related to fear development (Merckelbach, 1988).
3. The Non-associative account of fear acquisition. This theory is a variation of the preparedness theory. It states that people are born with innate fears and learn how to overcome them. Clinical phobias are thought to occur later in life and are due to the failure of habituation of the fear (Armfield, 2006). Critics of this theory believe that results of previous studies conducted could have been explained by other theories (Davey, 2002).
4. Davey’s contemporary conditioning model. This model was proposed in order to aid in explaining why many individuals do not develop a phobia after a traumatic life event is experienced and also the irregular distribution of phobias within a population. This theory states that a conditioned stimulus will prompt a “cognitive representation” of an unconditioned stimulus. This is done through learned associations. Additionally, early exposure to the conditioned stimulus, before it is paired with the unconditioned stimulus has an inhibitory property (Davey,

1989). This is known as latent inhibition. Davey (1989) went on to study dental fear and noted that patients with trauma or painful experience and did not show signs of fear reported having previous history of negative experiences. Moreover, he states that certain people following a traumatic experience use "unconditioned stimulus devaluation" in which the unconditioned stimulus is neutralised by various coping strategies and eliminate the fear. Critics of this theory state that coping strategies like distancing oneself increased worry and fear (Folkman and Lazaras, 1988).

5. Cognitive theories of fear acquisition. An example is Bandura's self-efficacy theory (Bandura 1977), which states that the person's self-efficacy in executing a certain action that is connected to the phobic stimulus, and the outcome of executing the action on the phobia are critical in its development. However, no link has been established between behaviour development and self-efficacy and also fails to consider the roles of anxiety and fear. A second theory of cognitive fear acquisition is Beck and Emery's theory of maladaptive cognition. It states that anxious people are fixated on the threat of harm and danger from the phobia. This plays an essential role in not only the aetiology but also the maintenance of the phobia, which may make eliminating it difficult (Armfield, 2006).
6. The three pathways of Rachman. The "traditional" classical conditioning theory does not account for the absence of fear in some people when a fear evoking stimulus is present, and it does not account for unfair distribution of fear. It also fails to explain the acquisition of fear vicariously (Armfield, 2006). Therefore, Rachman (1977) theorised three possible pathways. The first is classical conditioning, where fear is acquired through conditioning. The fear is strengthened by number of repetitive exposure to the fear evoking stimulus and the intensity of the fear and/or pain associated with the stimulus there can also be a secondary stimulus which is similar to the primary stimulus that can elicit a similar reaction. The second pathway is vicarious acquisition, where fear is

acquired as a result of indirect exposure of a stimulus, which is linked to a terrifying experience. There is no history of prior exposure to the fear evoking stimulus. (Rachman, 1977). The same method is also used to learn behavioural traits and emotional responses (Bandura et al., 1969). The final pathway proposed by Rachman (1977) is “fear acquisition by transmission of information and/or instructions”. Similar to vicarious acquisition, there may not be any history of past experience with the stimulus. The fear in this case is more unlikely to be severe. This method of fear acquisition is the basis for common fears. Rachman’s theory has been supported by the literature. (ten Berge et al., 2002)

1.1.2 Aetiology of Dental Anxiety:

Dental anxiety has a multifactorial aetiology, with numerous modifying factors. These include the child’s temperament to fear, sensitivity to pain, negative emotions, and coping styles. Attitude of the parent’s negative information and previous painful experiences can play a role with coping strategies (Majstorovic and Veerkamp, 2004). One classification of the aetiology of dental fear is based on dividing it into two groups: endogenous, related to general fear, and exogenous, related to conditioning. The latter is more common in children (ten Berge et al., 2002). However, it has been reported that dental fear is linked to certain phobias like the fear of flying, heights, and enclosed spaces (Milgrom at al., 1995). Another classification is based on the cause of the specific phobias. They include the following (Liddell and Locker, 2000):

- Patients with a conditioned fear from a particular stimulus
- Patients with multi-phobic or trait anxiety symptoms
- Patients with anxiety about a specific part of dental treatment
- Patients who doubt members of the dental personnel

Although most anxiety related disorders have a heritable component, the heritability of dental anxiety and fear is poorly understood. There is, however, an environmental component, in which dental care that was either painful or unpleasant, may contribute to

dental anxiety and fear in both adults and children (Ray et al., 2010; Townend et al., 2000). Ray and co-authors (2010) did find that heritability of dental fear was high in female twins and low in male twins. Though the development of dental anxiety in children does follow the three pathways of Rachman, the same cannot be said about dental phobia in children. The conditioning process either showed minimal or negative associations, meaning exposure may even act as a form of prophylaxis. The modelling pathway of developing dental phobia in children can be linked to the mothers anxiety and past experience, although in most studies it was noted that no direct observation was present (Townend et al., 2000). The information pathway, in which children either heard or saw “terrifying” events, can develop common phobias, however dental anxiety and dental phobia was not covered in the study (Ollendick and King 1991). Furthermore, it was reported that there is a strong relationship between dental fear and the dentist’s behaviour, which adolescents being nine times more likely to be very anxious if the dentist showed a lack of empathy (Townend et al., 2000).

A systematic review by Zhou and colleagues (2011) reached a similar conclusion; giving specific instructions, showing empathy and giving a reassuring touch with verbal encouragement all discouraged dental anxiety and fear, while criticism for rebellious behaviour, coercion and restraining all had negative effects. Another factor thought to be involved in dental fear and anxiety is invasive and/or painful dental treatment, though most studies were retrospective in nature and inconsistent findings were reported in children. However, it was found that more check-ups prior to dental treatment may aid in the reduction of dental fear (ten Berge et al., 2002; Davey, 1989). This will aid in eliminating any uncertainty the child has, which plays a role in anxiety development. Furthermore, the appearance of the staff may trigger anxiety, especially when the child has a ‘white coat phobia’ (Fayle and Tahmassebi, 2003). Although anxious patients who avoid dental treatment due report more invasive treatment when compares to non-anxious avoider, more of the former group seek treatment in the later stages of dental pathology, where severe pain is present (Liddell and Locker 2000). Moreover, the

patient's subjective perception of the dental visit was more important in the development of fear than the actual dental treatment (ten Berge et al., 2002).

1.1.3 Dental Anxiety Effect and Outcome:

It has been reported that children who are fearful of dental treatment avoid dental treatment, which generally has a detrimental effect on the carious dentition. If treatment is sought out, poor behaviour is exhibited. This has led to the development that dental anxiety is a predictor of dental caries; however, there are conflicting results (Taani et al., 2005).

Milgrom and co-authors (1995) divided the possible feared dental stimuli into three groups. These included highly invasive procedures, such as injections or drilling, victimisation, such as fearing strangers, and finally less invasive procedures, such as a dental exam. Fear of injections, namely blood injury injection phobia (BIIP) has been shown to overlap with dental anxiety. Vika and co-workers (2008) reported that 3.3% of 18year olds avoid dental treatment when a dental injection is required. Moreover, children who have a fear of dentists not only have more carious teeth; they also have more teeth missing as a result of caries. Oral health is then perceived in a more negative fashion (Carillo-Diaz, et al., 2013b). The quality of life is reduced as a consequence of the dental phobia. This is thought to be due to the consequence of poor oral health status and the psychosocial effect of the phobia (Agdal et al., 2012). The quality of dental treatment performed is also affected, as a delay in seeking proper treatment due to dental anxiety often means that conservative dental treatment is not a feasible option (Newton et al., 2012). As proposed by Berggren and Meynert (1984), the dental anxiety cycle can be challenging to break; fear and anxiety will often lead to avoidance of care, which will worsen the present dentition leading to feelings of guilt and shame that will further increase fear and anxiety.

1.1.4 Dental Anxiety in the UK:

Nuttall and co-authors (2008) reported that 75% of children in the UK have no anxiety at all and less than 4% of those interviewed had a phobia so severe that it affected their dental attendance. Moreover, the younger children in the study who were more anxious were inclined to have more active caries than those who were not anxious. Having extractions, whether under general or local anaesthesia, was shown to be linked to an increase in dental fear. Having restorative treatment did not seem to be associated with dental anxiety in the young, but in the 12 years and 15 years of age, anxiety was increased.

1.1.5 Measures of Dental Anxiety:

Dental anxiety can be assess by using various approaches, with questionnaires and rating scales being the more common method (Welbury et al, 2012). Behavioural assessments can also be performed as well to evaluate anxiety levels. In addition, anxiety can also be assessed through the use of psychometric scales by means of a questionnaire with categorical answer scales. Furthermore, a projective technique may be utilised by using a questionnaire with a continuous answer scale. Indirect measures such as measuring heart rate and palmar sweat index (PSI) have also been implemented to measure anxiety levels in children (Klingberg et al., 1995). The measuring tools should be quick, relevant for children and their dental experience and simple to analyse and score (Buchanan, 2005). The tool should also be valid in its measure of anxiety, which may be problematic for indirect measures involving physiological measures (Buchanan and Niven, 2002). As of yet, there has been no standardised method to evaluate dental anxiety; most methods involving questionnaires have not shown constant reproducibility and reliability, and physiological and observational scales are poorly developed (Welbury et al., 2012).

1.1.5.1 Behavioural scales

The use of patient administered questionnaires may not be suitable for children of young ages, as their understanding and vocabulary may not be well developed. In these cases,

behavioural scales may be used (Welbury et al., 2012). Frankl and co-authors (1962) originally developed the Frankl rating scale by measuring behaviour in five dental scenarios; parental separation, oral examination, prophylaxis, x-ray and departure from clinic. It is explained in the Table 1.1:

Table 1.1 Frankl Rating Scale

Category (symbol)	Definition
Definitely negative (--)	• Refuses treatment • Forceful crying • Other evidence of severe negativity
Negative (-)	• Unwilling to accept treatment • Uncooperative • Some evidence of negative attitude that is not pronounced
Positive (+)	• Accepts treatment • Cautious at times, but willing to comply with dentist • Reserved at times, but follows dentist's directions
Definitely positive (++)	• Good rapport with dentist • Shows interest in dental procedures • Shows signs of enjoyment and laughter

The scoring of the behaviour has been conducted in various ways. An overall rating of the child's behaviour is usually given, however, the sum of the individuals' behaviour on certain occasions may provide a more accurate score (Dean et al., 2010; Aartman et al., 1996)

The Houpt scale scores behaviour on four distinct criteria, which include crying, cooperation, apprehension, and sleep. The dentist rates the child in five minute intervals. The score is then summed up and divided by the number of intervals. It can be a reliable tool, but should only be used to rate the patient's response to specific aspects of dental treatment. The rating is described in the Table 1.2 (Hosey and Blinkhorn, 1995):

Table 1.2 Houpt Scoring criteria

Criteria	Scoring
Crying	1. Screaming 2. Continuous crying 3. Mild and intermitted crying 4. None
Cooperation	1. Resists violently and disrupts treatment 2. Treatment difficult due to excessive movement 3. Minor and intermitted movement 4. No movement
Apprehension	1. Disobeys all instructions, hysterical 2. Tremendously anxious, delays treatment and disobeys some instructions 3. Mildly anxious and complies with support 4. Follows instructions. Child is calm and relaxed
Sleep	1. Fully awake 2. Drowsy 3. Sleeps intermittently 4. Sound asleep

Venham's "Anxiety Rating Scale" and "Uncooperative Behaviour Rating Scale" (Venham et al., 1980) uses an ordinal scale from zero to five; "0" is relaxed, smiling and able to communicate with the dentist for the anxiety scale, and total cooperation for the behaviour scale, and "5" represents a child who is out of control in the anxiety scale and general protest in the behaviour scale. It was shown that the distance between each scale point was relatively equidistant (Venham et al., 1980).

Other behavioural assessment tools include the visual analogue scale, a 100mm line where the rater marks the level of anxiety, and the global rating scale, where 1 is considered poor and 5 is rated as excellent (Hosey and Blinkhorn, 1995).

1.1.5.2 Self-reported anxiety measure (Psychometric and Projective)

Venham Picture Test (VPT):

VPT consists of a series of eight pairs of pictures showing a male cartoon figure that was developed by Venham and Kremer (1979). Each frame depicts an anxious and non-anxious child, with 1 point given every time the child selects the anxious male cartoon (Venham and Kramer, 1979). Aartman and co-authors (1997) stated that the reliability of

VPT has not been researched significantly, and requires further studying. Although the VPT can differentiate between fearful and non-fearful children, the correlation between VPT and other dental anxiety measures has been rated low to moderate (Porritt et al., 2013; Aartman et al., 1997). Limitations of this method are related to the pictures; all of them illustrate a male character that may be difficult for young girls to relate to. Moreover, some of the pictures are vague in the emotion expressed (Buchanan and Niven, 2002).

Facial Image Scale (FIS):

The FIS consists of five “genderless” faces, ranging from very happy to very unhappy; the highest score was for the unhappy face. Children are told to select which face they feel represents them. It may be used as a measure by itself, or combined with other measures (Porritt et al., 2013). Although it has been shown to be correlated to VPT (Buchanan and Niven, 2002), the FIS has some limitations. The measure of anxiety is at a specific point during treatment and is not a state of anxiety. However, this measure is suitable for young children and those with limited cognitive development (Porritt et al., 2013).

Smiley Face Programme (SFP) and Smiley Face Programme – Revised (SFP-R):

The SFP was developed by Buchanan (2005) and measures for items related to train dental anxiety; having a dental appointment the next day, sitting in the waiting room, about to have tooth drilled and about to receive dental injection. The scale has seven faces for the child to choose from, with the fourth face being neutral. This measure is computerised, which makes it interactive for the child and assists in data collection, however, it is only limited to children who can understand how to use the computer. Moreover, the SFP is short and relevant to dental anxiety in children (Buchanan, 2005). Buchanan later modified the SFP, adding an item to assess anxiety with extractions, updating the pictures and amending the instructions, making it more suitable for younger children. The SFP was found to be suitable for children as young as 6 years of age, while

the SFP-R was suitable for children as young as 4 years of age (Buchanan, 2010; Buchanan 2005).

Children's Fear Survey Schedule – Dental subset (CFSS-DS), and Dental Fear Survey Schedule – Short Form (DFSS-SF):

The CFSS-DS is a commonly used anxiety measuring tool with high reliability (correlation coefficient ranging from 0.82-0.9). Validity, on the other hand, was variable with results showing moderate to good validity. The scale is often used when large groups are involved (Klingberg and Broberg, 2007; Aartman et al., 1997). It consists of 15 scenarios that are scored on a five point scale with a score of 1 denoting no fear and a score of 5 denoting very frightened. The various scenarios are categorised into three different groups, which are invasive procedures, potential victimisation and non-invasive dental procedures (Porritt et al., 2013; Buchanan, 2005). Cut-off readings are variable depending on the study. Klingberg and Broberg (2007) reported cut-off values for fearful ranging from 37-42, while Porritt and co-authors (2013) reported scores above 32 as anxious and scores greater that 38-39 as very anxious. The CFSS-DS, however, fails to address certain factors related to dental anxiety; these include the child's physical response, behaviour and thoughts. Additionally, the questionnaire has a few unrelated questions, such as having treatment carried out in a hospital, and is also quite time consuming. An eight itemed dental survey that scored in a similar fashion, the DFSS-SF, was then developed. However, the limitations of the CFSS-DS are still apparent in the DFSS-SF (Porritt et al., 2013; Buchanan, 2005).

Dental Anxiety Scale (DAS) and Modified Dental Anxiety Scale (MDAS):

The DAS was initially developed by Corah (1969). It comprises of four questions scored from one to five with a higher score being more anxious. The questions were regarding the following topics:

- Anticipating going to the dentist the following day
- Anticipating the appointment while seated in the waiting room

- Anticipating the dentist working on your teeth while seated in the dental chair and the dentist is preparing the drill
- Anticipating the dentist cleaning your teeth while seated in the dental chair and the dentist is preparing the instruments to “scrape your teeth around the gums

The cut-off score for an anxious patient ranged from 12-16, with the upper quartile being selected in studies on adults (Aartman et al., 1997). Additionally, it can also be combined with the FIS. Although validity was high, this scale was largely used on an adult population. Furthermore, it neglects to assess anxiety related to local and general anaesthesia, and inhalation sedation (Humphris et al., 1998). Since the DAS was developed namely for use in the adult population, the design of the DAS may not be suitable with children (Porritt et al., 2013).

The MDAS was developed to tackle some short-comings with the DAS by Humphris and colleagues (1995). With the DAS, the answers for all the questions were not standardised. The answers also included symptoms that may not be experienced by all subjects answering the questionnaire. They therefore changed all the answers from not anxious to extremely anxious. A fifth item concerning local anaesthetic injection was added. A cut-off of 19 out of a possible 25 for dental phobia is used with this scale (Humphris et al., 1995).

Although the MDAS did address some of the issues with the DAS, it was still developed using adult subjects, hence an eight items questionnaire entitled the Modified Child Dental Scale (MCDAS) was developed by Humphris and co-authors (1998). The questions and answers were amended and an additional three more questions were added. The scoring was from relaxed and not worried (1) to very worried (5). The questions were focused on the child’s feeling towards (Humphris et al., 1998):

- Generally going to the dentist
- Your teeth being looked at
- Your teeth being scraped and polished
- An injection in your gums

- A filling being done on your teeth
- Your tooth being taken out
- Being put to sleep for the treatment
- A “gas-air” mixture is given to you that will make you feel comfortable, but will not make you sleep for treatment

Howard and Freeman (2007) further modified the MCDAS by adding 5 faces (MCDAS-f) and found that it was suitable for children as young as 5 years of age, while the MCDAS was for children aged 8 years and older (Buchanan, 2010; Howard and Freeman, 2007).

Indirect analysis of anxiety:

Indirect analysis of anxiety involves measuring physiological responses to anxiety and requires specialised equipment (Klingberg et al., 1995). The assumption made was that although physiological measures are direct measures of anxiety, any increase in arousal during dental treatment was linked to stress and anxiety with the dental visit. However, Venham and Quatrocelli (1977) found that changes in heart rate were not associated with anxiety. Another studied physiological response is the palmar sweat index. Lore (1966) stated that emotional sweat areas vary from the heat regulatory area, with the emotional areas being the palm of the hands, soles of the feet, armpits, groin, forehead and the upper lip. He concluded that anxiety was associated with increased sweating when using the first three fingers to measure the palmar sweat index.

1.2 Sedation

Anxiety control involves using various behaviour management techniques, both pharmacological and non-pharmacological. For children who are cooperative or potentially cooperative, non-pharmacological methods of behaviour management may be a suitable method of anxiety control; however, pre-cooperative and uncooperative children may require conscious sedation or general anaesthesia (GA) (Welbury et al., 2012). Nonetheless, the decision for which method of anxiety control is to be used should

be made on a patient and treatment specific basis (Scottish Dental Clinical Effectiveness Programme (SDCEP), 2012). Factors that are considered are:

- Age of the patient
- Degree of surgical trauma and treatment complexity
- Anxiety level of the patient
- Response to previous sedation or expected response to sedation
- Medical status, as per the ASA classification (American Society of Anesthesiologists, 2006)

After the publication of 'A Conscious Decision' (Department of Health, 2000), it was recommended that the use of GA for dental treatment should only be carried out in hospital settings, and only when all other alternatives, such as sedation, have been exhausted. However, when sedation is to be considered, it should be used as an adjunct to behaviour management techniques, and all pharmacological and non-pharmacological methods should be considered when treatment planning each individual case (SDCEP, 2012; Welbury et al., 2012).

The aims of using sedation in children during treatment are to assist in reducing fear and anxiety, and to enhance pain control. It also reduced the movement of the child during treatment (National Institute for Health and Care Excellence (NICE), 2010). Sedation also prevents deal fear from developing when used on children "prophylactically" in situations that may possibly be traumatic. Furthermore, it supports the dentist by facilitating the completion of the treatment. The stress and unpleasant emotions experienced by the dentist will also be reduced, in addition to preventing burn-out (Welbury et al., 2012; European Academy of Paediatric Dentistry (EAPD), 2003).

The American Society of Anesthesiologists (ASA) (2009) stated that sedation was a continuum of four stages, and it was difficult to calculate how the patient would respond to sedation. The practitioner should be capable of rescuing the patient from a level of

sedation deeper than the level of sedation used. Descriptions of these stages are presented in Table 1.3:

Table 1.3: Stages of sedation

Stage of sedation	Definition
Minimal sedation – Anxiolysis	• Drug induced state • Patient responds to verbal command • Cognitive function and coordination impaired • Protective reflexes and cardiovascular function maintained
Moderate sedation – Conscious sedation	• Drug induced decrease in consciousness • Patient responds purposefully to verbal commands and/or light tactile stimuli • Respiration, airway and cardiovascular functions maintained
Deep sedation	• Drug induced decrease in consciousness • Patient not easily aroused, but can respond purposefully • Airway and breathing impaired, but cardiovascular functions usually maintained
General anaesthesia	• Drug induced loss of consciousness • Patient cannot be aroused • Airway and breathing needs to me maintained with positive pressure ventilation • Cardiovascular function impaired

Another term used in sedation is ‘dissociative sedation’, which is defined as a trance-like condition that is brought upon by ketamine. Protective reflexes are maintained along with spontaneous breathing and cardiopulmonary functions (Kraus and Green, 2006).

1.2.1 Classification of Sedative Drugs:

Sedative hypnotics are commonly used for procedural sedations. They include benzodiazepines, barbiturate, propofol and chloral hydrate. Due to the lack of analgesia produced with the drugs in this category, opioids are occasionally added for painful procedures. Inhalation sedation, whether alone or combined with local anaesthesia, and dissociative sedation are gaining popularity (Kraus and Green, 2006).

1.2.2 General Indications for Sedation

Sedation in children is indicated when procedures are too frightening or painful, or if the child is ill, in pain or has behavioural issues. The cost-effectiveness of sedation or treatment under local anaesthetic should also be considered (NICE, 2010). Deep sedation and the use of multiple drugs to induce sedation in anxious children are not recommended in the dental setting (Welbury et al., 2012; Hosey, 2002).

1.2.3 Conscious Sedation

The Standing Dental Advisory Committee (2003) defined conscious sedation as a technique involving the use of a drug or multiple drugs to induce a state of CNS depression in which dental treatment can then be carried out. Furthermore, the drugs used should have a large enough safety margin to avoid loss of consciousness. It is critical that verbal communication is always maintained; however, in cases of special needs where verbal communication may be lacking, then the usual method of communication for the patient should be maintained (SDCEP, 2012; Standing Dental Advisory Committee, 2003).

Various methods are used in sedation, however a systematic review conducted by Matharu and Ashley (2005) stated that due to the poor quality of research and the wide variety of methods used, they were unable to determined which single method was most ideal. The method can be classified as standard or alternative sedative techniques (Standing Committee on Sedation for Dentistry, 2007):

- Standard techniques being nitrous oxide/oxygen inhalation sedation alone, IV midazolam alone, and oral and transmucosal benzodiazepine
- Alternative techniques being inhalation sedation other than nitrous oxide/oxygen, combination of sedative agents or routes of administration, propofol either alone or in combination, and any form of conscious sedations in patients younger than 12 years of age, excluding nitrous oxide/oxygen inhalation sedation.

The primary route of administration for sedation in children is inhalation, followed then by IV, which should only be used in cases when inhalation sedation may not be successful (Wilson, 2013). Other routes of administration include oral, transmucosal, and intramuscular. These methods may be less invasive and more convenient for the child, but they are also non-titratable, hence the depth of sedation cannot be effectively measured (Kraus and Green, 2006). Oral and transmucosal administration of sedative agents should only be reserved for cases where titratable techniques cannot be used as the control of the depth of sedation is low (SDCEP, 2012). Other indications include difficulty with cannulation due to phobias, learning difficulties, or other disabilities, and anxiety levels too high for Nitrous oxide/ Oxygen inhalation. However, difficulty due to anatomical variations is a contraindication to oral and transmucosal sedation (Standing Committee on Sedation for Dentistry, 2007).

1.2.3.1 Indications and contraindications of conscious sedation

Conscious sedation can be used in cases of dental anxiety and phobia. It is also indicated when dental treatment is expected to be prolonged or traumatic. Certain medical conditions may impair the child's ability to cooperate, or may possibly be exacerbated with the added stress of the dental treatment; in these cases, conscious sedation is indicated. Furthermore, conscious sedation is indicated for children with special needs (SDCEP, 2012). Treatment need, and the complexity of the treatment should also be a considered when discussing the need of conscious sedation. For children with an ASA classification of I or II, conscious sedation can be performed in the community or specialty centres, however, children classified as ASA III or higher must have the sedation conducted in a hospital setting. Moreover, contraindications for the use of conscious sedation include children, below the age of one year and expectiant mothers in their first trimester (EAPD, 2003; Hosey, 2002).

1.2.3.2 Inhalation sedation

Nitrous Oxide

Inhalation sedation using nitrous oxide/oxygen mixture is the recommended method of sedation for children in the United Kingdom, with 83-96% of children successfully completing treatment (Soldani et al., 2010). The objectives of nitrous oxide/oxygen inhalation are to reduce fear and pain, and to improve patient behaviour and cooperation (Roberts, 1990a). There are three components in the use of inhalation sedation that are essential to improve success; administration of low to moderate concentrations of nitrous oxide that is titrated on an individual basis, comforting and semi-hypnotic cues, and proper equipment with fail safes and regular maintenance, including the use of scavenging systems (Kraus and Green, 2006; Roberts, 1990a). Nitrous oxide is an odourless and colourless gas that has a relatively quick onset, with in 1 minute, and recovery once stopped, due to its low solubility (Kraus and Green, 2006; Paterson and Tahmassebi, 2003). The concentration of nitrous oxide used varies from 30-70% with the remaining being oxygen, and depending on the amount used, different planes of sedation can be reached (Kraus and Green, 2006; Roberts, 1990a):

Table 1.4: Planes of Sedation with Nitrous oxide/Oxygen inhalation

Plan	Definition
Moderate sedation and analgesia	• Concentration of Nitrous oxide used : 5-25% • Patient may feel tingling in toes, fingers, oral cavity, back, hand and chest • Patient is relax, with an increase in pain threshold and a decrease in anxiety and fear. Patient still responsive • No side effects but hearing, vision, touch and proprioception impaired
Dissociative sedation and analgesia (psychosedation)	• Concentration of Nitrous oxide used: 20-55% • Patient may feel a sense of euphoria and detachment from the environment. Feeling of warmth, buzzing in ear, drowsiness and light headedness may be common • Patients responsiveness may be delayed • Nausea and vomiting possible but rare. Amnesia possible
Total Analgesia	• Concentration of Nitrous oxide used: 50-70% • Patients more likely to dream • Loss of ability to maintain mouth open and to respond to commands • Loss of consciousness possible

The planes of sedation for nitrous oxide/oxygen mixture are described above (Table 1.4). Due to the low solubility of nitrous oxide, accidental overdose is possible, and it is crucial to note signs and symptoms of over-sedation (Roberts, 1990a). These include an inability to maintain an open mouth, respond to the dentist and increase in movement, heart rate, blood pressure, respiration rate and sweating; the use of a mouth probe during inhalation sedation will make identifying mouth closure more difficult (Paterson and Tahmassebi, 2006; Roberts 1990b). Moreover, the patient may experience acute hearing, sleepiness, and visual impairment (Paterson and Tahmassebi, 2006). If over-sedation has occurred, the nitrous oxide concentration should be reduced by 10-15% increments; however, if no changes are visible, nitrous oxide should be stopped and 100% oxygen given. It is essential that after completing treatment with nitrous oxide/oxygen inhalation sedation, the patient should receive 100% oxygen for 3-5 minutes, followed by a period of ambience are to ensure there is complete elimination of nitrous oxide (Paterson and Tahmassebi, 2006; Roberts 1990a).

Although no serious morbidity has been reported (Soldani et al., 2010; Roberts 1990a), side effects can occur. These are more common when moderate or deep levels of sedation have been used; adverse effects include emesis (1-10% of patients), nausea and dizziness with emesis being more common with the use of fluctuating levels of nitrous oxide and oxygen, higher concentrations of nitrous oxide and lengthy appointments (Kraus and Green, 2006; Paterson and Tahmassebi, 2003). Other serious side-effects include diffusion hypoxia and bone marrow suppression; however, with the administration of 100% oxygen after the appointments and the short duration of dental appointments, the likelihood of these events occurring are minimal (Paterson and Tahmassebi, 2003). Moreover, a systemic review conducted by Faddy and Garlick (2005) shown no statistical significant of minor adverse effects from arising, with serious adverse effects, like oxygen desaturation and hypotension cannot be solely attributed to nitrous oxide/oxygen inhalation sedation.

Dentists and auxiliary staff members who are exposed to excessive amount of nitrous oxide can also suffer from adverse effects such as haematological disorders, such as pernicious anaemia and reproductive disorders, such as decrease in fertility and spontaneous abortion (Paterson and Tahmassebi, 2003). The published literature showed weak to moderate association, with most studies carried out before the use of a scavenging system was required (Rowland et al., 1995). Rowland and co-authors (1995) found that when using a scavenging system, there was no increased risk of spontaneous abortion in comparison to the unexposed group; 6.5% and 6.7% reported spontaneous abortion respectively with 10.2% reporting spontaneous abortion in the group working with no scavenging systems. Although genetic damage due to nitrous oxide exposure sedation was reported by Hoerauf and co-authors (1999), they stated that healthy individuals would have the capabilities to repair the genetic damage.

Indications and Contraindications of Nitrous Oxide/Oxygen Inhalation Sedation

The primary goals for the use of inhalation sedation using nitrous oxide/oxygen mixture is to manage medically compromised patients, reduce anxiety and fear and control gagging to levels where treatment can safely be carried out (Malamed, 2010; Paterson and Tahmassebi 2003; Robert, 1990b). Though most contraindications for nitrous oxide inhalation sedation are relative and not absolute, the risk of using nitrous oxide inhalation sedation should be balanced with the risks associated with GA; however, all cases should be assessed on an individual bases. Nevertheless, most adverse risks may be avoided when using oxygen concentrations greater than 20% of the inhaled mixture (Malamed, 2010; Paterson and Tahmassebi 2003). Below is Table 1.5 explaining the indications and contraindications for the use of nitrous oxide/oxygen inhalation sedation:

Table 1.5: Indications and Contraindications of Inhalation Sedation

Indication	Contra-indication
Mild to moderate fear and anxiety related to dental treatment	Claustrophobia; anxiety level may be increased when attempting to place the mask Mouth breathers
Acute dental problems where profound local anaesthesia cannot be achieved (acute pulpitis) and treatment of hypersensitive teeth	Myaesthaenia gravis and multiple sclerosis; muscle activity depressed, and using sedation may further depress muscle activity
Cardiovascular disease (angina, ischemic heart disease); high oxygen concentration reduces risk of ischemic attack	Children with behaviour problems; pre-cooperative and non-cooperative children may not breath through their nose and excessive crying will limited inhaled nitrous oxide
Respiratory disease (asthma); anxiety is reduced and non-irritating vapour is used hence reducing risk of asthmatic attack	Chronic obstructive pulmonary disease; increase concentrations of oxygen may lead to apnea as low concentrations of oxygen is the stimulus to breath
Dental treatment will be traumatic to the patient	Psychological disorders (compulsive personality and personality disorders); patients may resist the effects of sedation
Pregnancy; only after 1st trimester if needed	Pregnancy; best avoided during 1st trimester and may need to delay treatment in 3rd trimester.

Cerebrovascular disease as the risk of a hypoxic episode is low Epilepsy; anxiety and hypoxia reduced, both triggers for seizures	Upper respiratory tract infection and acute respiratory problems; inability to breathe through the nose and chance of possible cross contamination
Hepatic and renal disease; no biotransformation in the body	Diseases of closed spaces (bladder, ear infection, pneumothorax
Medically compromised patient where risks involved with GA is too great	Inability to communicate Learning difficulties
Cerebral palsy; can control movements	Patients with head injury; intracranial pressure is increased with nitrous oxide
Sickle cell disease; high oxygen concentration reduces risk of sickle crisis	Hypovolemia; loss of consciousness may occur faster

Adapted from Malamed, 2010; Kraus and Green 2006; Faddy and Garlick, 2005; Paterson and Tahmassebi, 2003 Hosey, 2002; Roberts, 1990b

Advantages and Disadvantages of Nitrous Oxide/Oxygen Inhalation Sedation

Nitrous oxide sedation can be used in a variety of patients including children, adults and those with special needs with minimal risk of adverse reactions, due to the large safety margin (Kraus and green, 2006; Roberts 1990a). Due to its low solubility, it can rapidly cross the alveolar arterial membrane, hence providing a rapid onset and recovery. It also has an anxiolytic and analgesic effect; significant analgesic effect is seen when nitrous oxide concentrations are 50% or more (Faddy and Garlick 2005). Furthermore, due to CNS depression, it can lead to amnesia although it is somewhat variable. However, concentration and intelligence may also be affected (Paterson and Tahmassebi, 2003). Additional advantages and disadvantages are summarised below (Malamed, 2010; Paterson and Tahmassebi, 2003):

- Advantages:
    - Non-invasive and no needles are needed

  - Easily titratable
  - Protective reflexes are maintained
- Disadvantages:
  - Not potent
  - Requires the patient to receive psychological reassurance by the dentist
  - Continuous flow needed
  - Nasal hood may interfere with treatment and seal may be broken; nasal hood requires the patient to breathe through their nose and it may be rejected
  - Nitrous oxide pollution; unscavenged nitrous oxide can have negative effects to staff and patients
  - The initial cost of equipment needed is quite high, and also requires regular maintenance

Sevoflurane

Sevoflurane is a sweet smelling and volatile gas which is used in GA, but has also been used as a form of conscious sedation with concentrations ranging from 0.1%-0.3%. It can also be combined with 40% nitrous oxide and the remainder being oxygen. The concentration used may vary from patient to patient and also from appointment to appointment (Soldani et al., 2010; Girdler et al., 2009). Lahoud and Averley (2002) found that when using concentrations of 0.1-0.3% sevoflurane with 40% nitrous oxide, can be more effective than nitrous oxide sedation alone; however, more training and additional cost are required. They concluded that when nitrous oxide alone fails, sevoflurane can be added in order to reduce the need of GA. Other agents such as halothane and isoflurane are too potent to be used in sedation, and further research is needed to assess their practicality in paediatric dentistry (Girdler et al., 2009; Hosey, 2002)

1.2.3.3 Oral sedation

The intra-oral route of sedation is one of the most convenient methods; no injections are required and less patient cooperation is needed when compared to inhalation sedation (Malamed, 2010: Girdler et al., 2009). However, due to the first pass effect, it is not as reliable. Oral sedation is an acceptable technique for pain and anxiety management. In order to effectively provide such a service, the operator should be trained in airway management, and should also be able to rescue the patient from a deeper level of sedation. Administration of the sedative agent should be performed in clinic where a suitable member of staff can monitor the patient, and not at home prior to the appointment; this will ensure that the correct dose is given (Malamed, 2010).

Oral Sedative Agents

Various agents have been used as oral sedatives. However, prior to sedation, a complete medical history, age, weight, and list of medications the patient is taking must be noted. Furthermore, the degree of anxiety and level of sedation required by the dentist must also be assessed. Although titration may not be possible during the appointment, 'titration by the appointment' can be done; the efficacy of sedation at the first appointment is assessed, following which the dose for the next appointment can be adjusted as needed (Malamed, 2010).

The properties of an ideal oral sedative are mentioned below (Girdler et al., 2009):

- Alleviate fear and anxiety
- Maintain protective reflexes
- Easily administered
- Free from any adverse effects
- Predictable durations and onset
- Quickly metabolised and excreted
- No active metabolites

The predictability of the sedative is dependent on the degree of anxiety, rate of absorption and the rate of metabolism of the patient. Absorption can be quite variable

from patient to patient and also within the patient's own biological factors (Table 1.6). The type of agent used can also play a role in the absorption rate. (Malamed, 2010: Girdler et al., 2009).

Table 1.6: Factors affecting absorption (Malamed, 2010: Girdler et al., 2009)

Drug Related Factors	Patient Related Factors
Lipid solubility of the drug; increase in lipid solubility results in increased absorption	pH of gastric fluid; acidity of stomach and small intestines can lead to drug deactivation
Dosage Form; aqueous solutions more readily absorbed than Tablets or oily solutions	Gastric emptying; time increases if fat content in stomach is high. Recommended to take any oral medicament with water
Size of drug particle; smaller the particles, greater the absorption	Surface area of mucosa; small intestine has larger surface area, hence more absorption occurs in duodenum than in the stomach
Drug acidity; organic acids freely diffuse across gastric mucosa, where drugs that are bases poorly absorbed	Hepatic 1st pass effect; drugs absorbed from GI pass through the hepatic portal system, which can inactive the drugs

Midazolam

Dosages

Midazolam can be given as an elixir or mixed with juices. Orally, the onset is 20-30 minutes; timing of onset and recovery may vary depending on first pass effect. In all cases where oral midazolam is used, a cannula should be placed to allow for reversal

with Flumazenil in cases of emergencies; however, it should be noted that rapid reversal may lead to sympathetic nervous system stimulation, while a titrated reversal may lead to only partial stimulation (Girdler et al., 2009; Kraus and Green, 2006). It should be noted that midazolam is not licensed as a sedative agent in children in the UK. Moreover, it should only be used in a hospital setting and under supervision of a qualified seditionist (Standing Committee on Sedation for Dentistry, 2007; SIGN, 2004).

The dosage used varies from country to country but ranges from 0.3-0.75mg/kg., with a maximum dose of 12mg. Tablets should be taken 1 hour before the appointment, while oral suspensions should be given 20-30 minute before their appointment, The peak concentration in plasma is reached in 20 minutes, and onset is within 45 minutes. It is eliminated from the system within 2 hours (Day et al., 2006; EAPD, 2003). The oral dose is higher than the IV dose as midazolam becomes inactivated from the 1st pass effect (Welbury et al., 2012).

Midazolam is contraindicated in children under 1 year old, and in those suffering acute illnesses, neuromuscular diseases, allergies, sleep apnoea, and hepatic dysfunction (EAPD, 2003).

Effect and Biochemical properties

The most commonly used oral sedative is midazolam. It is a lipophilic agent which exhibits anterograde amnesia, sedative, hypnotic, anxiolytic, anticonvulsant and muscle relaxing properties; however, they do not have any analgesic properties (Kraus and Green, 2006; EAPD, 2003). Midazolam is classified as a short acting benzodiazepine. Oral administration does not need much cooperation from the patient. The main concern with oral midazolam and other oral sedatives is that they cannot be titrated; this can lead to either over-sedation or under sedation, therefore patient assessment prior to sedation is important (Day et al., 2006; Kraus and Green, 2006). Midazolam may lead to cardiac depression although the risk is low when Midazolam is titrated in IV sedation. The risk of hypoxia and respiratory depression is higher when using benzodiazepines. As published

by the SDCEP (2012) there is a high level of evidence to suggest that oral midazolam is safe and effective; however, it is less controllable and less predictable than IV sedation (SDCEP, 2012; Kraus and Green, 2006). A rare complication that has been reported in a few children treated under oral midazolam is ‘disinhibitory behaviour’. The child patient may be crying, combative, disoriented, agitated and restless (Day et al., 2006; Kraus and Green 2006).

Guidance

Appropriate training is needed to understand drug interactions, airway management and basic life support (Lourenço-Matharu and Roberts, 2010; Dionne et al., 2006). Dionne and co-authors (2006) published a list of ‘Safety Considerations for use of Dental Organisation for Conscious Sedation’s Protocol’; however, their conscious sedation protocol is for the use of oral triazolam. They recommended that only adults and patients who are ASA classification I or II should be sedated with triazolam. Moreover, a full medical and drug history is needed. Furthermore, at least 18 hours of didactic training with at least 20 clinically oriented experiences with patients is required by the American Dental Association prior to conducting oral sedation. In the UK however, in order to be considered competent in sedative techniques for children, the dental practitioner should have completed at least 100 cases. Additionally, four years of post-registration experience and training is needed in paediatric cardio-pulmonary resuscitation (Lourenço-Matharu and Roberts, 2010). Appropriate equipment is needed to effectively monitor the patient. These include the use of a pulse oximeter and automatic blood pressure monitor which measures at 5 minute intervals. Moreover a portable positive pressure oxygen delivery system should also be available. Finally there should be a proper emergency protocol to deal with medical emergencies along with a suitable emergency kit, including flumazenil in cases where reversal may be needed (Dionne et al., 2006). As recommended by SDCEP (2012), pulse oximetry and blood pressure

monitoring is required when oral sedation is used; furthermore, the sedationist should be trained in other titratable methods of sedation and in venous cannulation.

Other Sedative Agents

Although midazolam is the most commonly used oral sedative, other agents can also be used and are mentioned in Table 1.7.

Table 1.7: Oral Sedatives

Drug	Dose	Onset and Duration	Effects	Other relevant Information
Chloral Hydrate	-500mg/5ml 30-45 min before appointment. -If failure to achieve desired level of sedation with 1 dose, don't give further dose or other medication	Onset: 15-30min Duration: 1-2hrs	GI Upset Can have an anxiolytic effect	-Fasting 2hrs prior - Bad taste. Diluted with water, juice acetaminophen -Never add to alcohol -Titrate by appointment -Effective for very young children or special needs -Possible risk of carcinogenicity
Hydroxyzine	Hydrochloride →10mg/5ml (syrup) Pamoate → 25mg/5ml (oral suspension Apprehensive → 50mg 2hr and 1hr before Less apprehensive→ single dose 50mg-75mg 1 hr before Aggitated → 25mg 3x daily day before then same as above Divided dose: 25mg night before, 25 mg morning of, and 25 mg 1hr before appointment	Onset: 30-60 min Duration: 1-2 hrs	Dry mouth, fever, skin rash Minimal respiratory and cardiac depression Hydroxyzine hydrochloride can have an antiemetic and antispasmodic effect	-Children older than 3 -Can be combined with nitrous oxide but reduce the doses -Should be noted that polypharmacy is not recommended in the UK
Promethazine	Tablet or syrup -1mg/kg	Often given in combination with other agents	Often given in combination with other agents	-Combined with other drugs -Sole agent not recommended for severe apprehension

Diazepam **(Valium)**	Pill or suspension Dosage: 0.2-0.5mg/kg: 4-6yrs → 2-5mg 3x before treatment with last dose 1hr before +6yrs → 5-10mg 3x before treatment with last dose 1hr before OR -Single dose 1 hr before -1/2 dose night before and ½ dose 1hr before	Onset: 1hr Duration: 2hrs Half-life: 24-48 hrs	Wide margin of safety Anterograde amnesia Similar side effects to Midazolam	-Used for hyperactive, highly anxious and excitable kids aged 4 yrs. or older -Effective in management of pre-op anxiety -Oral benzodiazepine unpredictable in kids
Ketamine	3-6mg/kg	Onset: 20min Duration: 35min	Hypertension, hallucinations, physical movements, increase salivation, increase risk of laryngospasm Cal have an amnesiac and analgesic effect	-Used for dissociative sedation -Fast acting -Wide safety margin

Adapted from Welbury et al., 2012; Malamed, 2010; EAPD, 2003; Hosey, 2002; Alfonzo-Echeverri et al., 1993; Badalaty et al., 1990

Dosages of any oral sedative agents are highly dependent on the weight of the child. It should be noted that the child may require 1-hour supervision post-operatively when in recovery to assess for any side-effects (Welbury et al., 2012). Although in the United Kingdom, oral sedation only involves the use of a single sedative agent, commonly midazolam, in other institutions polypharmacy may be practiced with the prescription of various combinations of oral sedatives. It should be noted that in the United States, there is no consensus on the dosages of agents that are used in combination therapy (SDCEP, 2012; Chowdhury and Vargas, 2005).

Indications and contraindications

According to the BDA guidance on conscious sedation (2011), all titratable forms of sedation should be exhausted. Oral midazolam in indicated in children who are classified as pre-cooperative and also in special needs cases; however, oral midazolam is contraindicated in cases of hypersensitivity to the sedative agent, morbid obesity, airway obstruction and sleep apnoea (Meechan et al., 1998).

Advantages and disadvantages

The advantage and disadvantages are summarised in Table 1.8 (Meechan et al., 1998)

Table 1.8: Advantages and Disadvantages of Oral Sedation

Advantages	Disadvantages
• Cheap and non-invasive • Ease of administration • Low risk of adverse reactions	• Compliance is still needed • Variable onset and absorption • Not titratable hence cannot alter sedation depth • Short duration of action

Adapted from Meechan et al., 1998

Literature on various oral sedative agents

Chowdhury and Vargas (2005) conducted a retrospective study comparing a combination of chloral hydrate, meperidine and hydroxyzine to oral midazolam in paediatric dental patients; both groups were also given 50% nitrous oxide / oxygen inhalation sedation. Success was based on level of movement, cooperation, use of restraints and whether treatment was completed. They reported that the combination therapy had a significantly higher success rate than midazolam with children being three times more likely to complete treatment when the combination therapy was used. Oral midazolam was found to be 70% successful whereas the combination therapy was 90% successful. There was no significant difference reported between heart rate and desaturation with the type of drug regimen used.

Another study conducted by Avalos-Arenas and co-authors (1998) looked at whether adding hydroxyzine to chloral hydrate affected the behavioural and sedative response of the paediatric patient in a randomised double blinded study. They reported that the overall behaviour of the child did not differ in either the choral hydrate only or when combined with hydroxyzine; however, a deeper level of sedation and higher rates of desaturation were reported in the combination group.

Fraone and co-authors (1999) assessed the effect of oral midazolam on three age groups; 24-35 months, 26-47 months, and 47-59 months. The Ohio State behaviour rating scale was used to assess behaviour and the heart rate, oxygen desaturation and blood pressure were measured as physiological parameters. They reported no statistical significant difference in the behaviour across the age groups. Moreover, no significant effects on physiology were reported. Their study concluded that oral midazolam could promote ‘quiet behaviour’ in up to 49% of cases within the age range studied.

In a study comparing oral midazolam with inhalation sedation using nitrous oxide/ oxygen gas mixture for extractions of primary teeth in an older age group (5-10 years) Wilson and co-authors (2006) found that oral midazolam is as safe and effective as nitrous oxide sedation. Although Midazolam was found to be acceptable in 59% of children and

preferred in 36% of children, nitrous oxide sedation was rated as more acceptable and also more preferred option of sedation (Wilson et al., 2006). However, the flaw in the study was in its design; as a crossover study, this may lead to a carryover effect. Additionally the sample size was small which may have had a serious effect on the precision of the study. A review of the literature published by NICE (2010) showed that although there was a moderate quality of evidence showing that oral midazolam has a shorter induction, recovery, and total time, there was no significant difference in procedural time and patient preference when data was pooled; the data from Wilson et al., (2006) was not available and hence not included in the meta-analysis conducted (NICE, 2010).

1.2.3.3 Intravenous sedation

Intravenous sedation is only recommended in a few cases and should not be used for pre-cooperative children. The current policy in the UK is that IV sedation should only be used for children aged 16 years and above. The recommended method is the use of a titrated dose of a single drug; often midazolam is used for adolescents who are both emotionally and psychologically stable (SIGN, 2004; Hosey, 2002). Fixed and bolus doses are not acceptable methods of administration as they are not titratable. However, continuous infusion of drugs, either as a single dose or in combination may be justified in some cases; the experience level of the practitioner, the training level of the sedation team and the facilities available have to be all taken into consideration (Standing Dental Advisory Committee, 2003).

Administration and Monitoring:

Prior to administering the IV agent, a pre-operative assessment must be conducted to assess the suitability of the patient. Additionally, proper fasting instructions can be given and informed consent gained. A full medical history, including all the medications that the patient is taking must be recorded (Malamed, 2010).

A secure IV access is needed, not only for administering the sedative drug but also administering the reversal agent; the cannula should be kept till recovery. Sites for the cannula include either the dorsum of the hand, or the antecubital fossa. The dorsum of the hand is predominantly selected as the first choice, as the veins are superficial and clearly visible. Although the veins might move around if the skin is not taught, the underlying bones of the hand can be used to gain additional support; however the dorsum of the hand may be a painful site for venepuncture and topical analgesia is often required. The antecubital fossa, although not being the primary choice has large and well tethered veins; nevertheless, the veins are in close proximity to other major vessels and structures. The selection of the site depends on the experience of the practitioner (Malamed, 2010; Girdler et al, 2009).

Titration is achieved by incrementally administering the sedative agent according to the patient's response. The clinician must continue to communicate with the patient and look for signs of adequate sedation level, which are as follows (Malamed, 2010; Girdler et al, 2009):

- Slurring and slow speech
- Calm demeanour
- Willing to undergo dental treatment
- Delayed response to verbal commands
- Positive Eve's sign (cannot move finger to nose)
- Verill's sign (upper eye lid at level of mid pupil)

The signs may not all occur; it is frequently the case that only 2-3 signs may be present. Moreover, the signs may not be dose dependent and may vary from patient to patient and visit to visit. Factors that should be considered include the extent of fear, the amount of sleep for the previous night, and the level of stress that patient has.

Monitoring of the patient is critical and should involve both clinician and electrical monitoring as described in the Table 1.9:

Table 1.9: Methods of Monitoring Conscious Sedation

Clinician Monitoring	Electrical Monitoring
Patency of airway	Blood pressure
Respiratory pattern	Pulse oximetry
Pulse	Heart rate
Skin colour	End tidal CO_2
Level of consciousness	

Induction and Recovery

The induction process depends on the plasma concentration of the sedative drug; it is affected by the rate of injection, cardiac output and circulatory blood volume. The sedative agent then travels to the central nervous system through the arterial circulations and passing the blood brain membrane. Since the brain is highly perfused, a higher concentration of the sedative drug will be reached. With time, the sedative agent will be redistributed to the adipose tissue, leading to a decrease in plasma concentrations and reversing the blood-brain gradient. The sedative agent will then travel from the brain into the blood stream for elimination by ways of the kidney and/or liver (Girdler et al 2009).

Agents for IV Sedation

According to the intercollegiate advisory committee for sedation in dentistry (IACSD), IV midazolam in a titrated dose is commonly the agent of choice (IACSD, 2015). However, IV midazolam is not routinely recommended for conscious sedation in paediatric dental procedures in the UK; deeper levels of sedation than intended may be produced and the reaction and acceptance of children to intravenous sedation may be unpredictable. Furthermore, training of all staff involved is required (Mcintosh et al., 2014: Averley et al., 2004; Wilson et al., 2003).

Intravenous midazolam is usually administered in a concentration of 1 mg/ml, with a maximum single dose of 6-8mg; the maximum dose is 10mg. It is titrated at a rate of 1 mg (1 ml) per minute until signs of adequate sedation level are visible. Once this effect is achieved, titration ceases (Malamed, 2010). Onset of sedation takes 2-3 minutes, with a duration of 45-60minutes (Kraus and Green, 2006).

As with oral midazolam, monitoring for signs of respiratory depression is crucial in IV administration of midazolam; respiratory depression is dose dependent and increases with midazolam when combined with opioids or alcohol (Kraus and Green, 2006). However, the IACSD has stated that multiple anaesthetic drug techniques for use in conscious sedation should only be considered by skilled professionals who are trained in their use. Furthermore, these methods of conscious sedation should only be used when there is a clear clinical justification to do so (IACSD, 2015).

In cases where midazolam alone does not provide satisfactory anxiolysis, a single dose of fentanyl may be given prior to IV midazolam. This drug regimen should only be used in patients who are classified as ASA Class I or II and on patients older than 16 years of age (IACSD, 2015). fentanyl is an opioid which, as a single dose can produce sedative effects. It can be titrated every 3 minutes to a maximum of 50 µg/dose. Onset of sedation can be seen in 3-5minutes with sedation lasting up to 60minutes. However, at lower doses of 1-2 µg/kg, it can be combined with midazolam for painful procedures (IACSD, 2015; Kraus and Green 2006).

For longer procedures, IV midazolam can be combined with propofol. This form of conscious sedation involves initially inducing sedation with titrated IV midazolam, and maintaining the sedative state with a continued infusion of IV propofol. A dedicated sedationist is needed when using propofol. Propofol has no analgesic properties; however, it has minimal post-operative confusion and is anti-emetic (IACSD, 2015; Melamed, 2010). Propofol given at a titrated dose of 0.5-1mg/kg will result in a sub-hypnotic state within 3-5minutes. The dose should then be maintained at 3-4.5mg/kg/hr.

Due to the narrow safety margin of propofol, its use as a sedative agent is not recommended in children (Melamed, 2010; Hosey, 2002).

The IACSD (2015) did discuss various patient controlled sedative (PCS) techniques; they stated that although PCS using Propofol has been studied, the reliability, safety, and availability need further investigation. Moreover, with regard to PCS, using midazolam, itis not currently being used as a form of conscious sedation within the UK (IACSD, 2015).

Indications and Contraindications

IV sedation is more suitable for adults; in the UK, the age at which IV sedation can be done is 16 years and older. It is indicated for patients suffering from severe dental anxiety, and those undergoing traumatic surgeries. Both gagging and swallowing reflexes must be maintained. Patients with mild medical conditions such as mild asthma or mild learning disabilities may similarly benefit from intravenous sedation.

Patients who have a reported history of allergy to the sedative agent to be used or have drug dependency issues are not candidates for IV sedation. Moreover, if they have renal or hepatic impairments or have severe psychiatric disorders, IV sedation is contraindicated. Pregnant mothers or mothers who are breast feeding should not receive IV sedation as well (Melamed, 2010; Girdler et al, 2009).

Advantages and Disadvantages (Melamed, 2010; Girdler et al, 2009, Meechan et al, 1998):

With certain agents, such as midazolam, there is a wide margin of safety with its use. Onset is rapid with recovery often occurring within a reasonable period of time, and the patient can be sent home on the same day. With IV sedation, titration of the sedative agent to the patient's need is possible. Additionally, IV access is preserved throughout treatment; however, cooperation is needed to gain venous access at the start of the treatment. Moreover, the patient's perception and response to pain may be altered, with

some agents not producing significant analgesia. Adverse reactions are also more pronounced, with the risk of respiratory depression increased when carrying out IV sedation. The operator should be aware that once the agent is administered, they must wait for the patient to metabolise and eliminate the drug naturally. If an overdose occurs, the management involves basic life support and also the administration of an antagonist. The antagonist only blocks the effect of the drug and does not increase the rate of metabolism.

1.3 Quality Of Life

Oral health related quality of life (OHRQoL) is a fundamental component of general health and well-being. It is the subjective assessment of the impact of diseases in the oral environment on everyday life. The magnitude of factors such as, frequency, severity and duration may affect the patients experience and perception of their life overall (Gilchrist et al., 2014; Sischo and Broder 2011; Petersen, 2003).

1.3.1 Quality of Life Measures

An appropriate measure must be reliable and valid. Furthermore, patient involvement is needed in order to evaluate interpretability of the measure and whether the items reflect what is important to the patients and assessors. The measures should consider cultural or language barriers and be adapted accordingly (Gilchrist et al., 2014).

When measuring OHRQoL, both negative and positive perceptions of oral health outcomes should be investigated, as elements like optimism and resilience can affect one’s quality of life (i.e. how well patients can cope with a certain illness) (Sischo and Broder, 2011). Various fields have been explored, and are summed up in Figure 1.1:

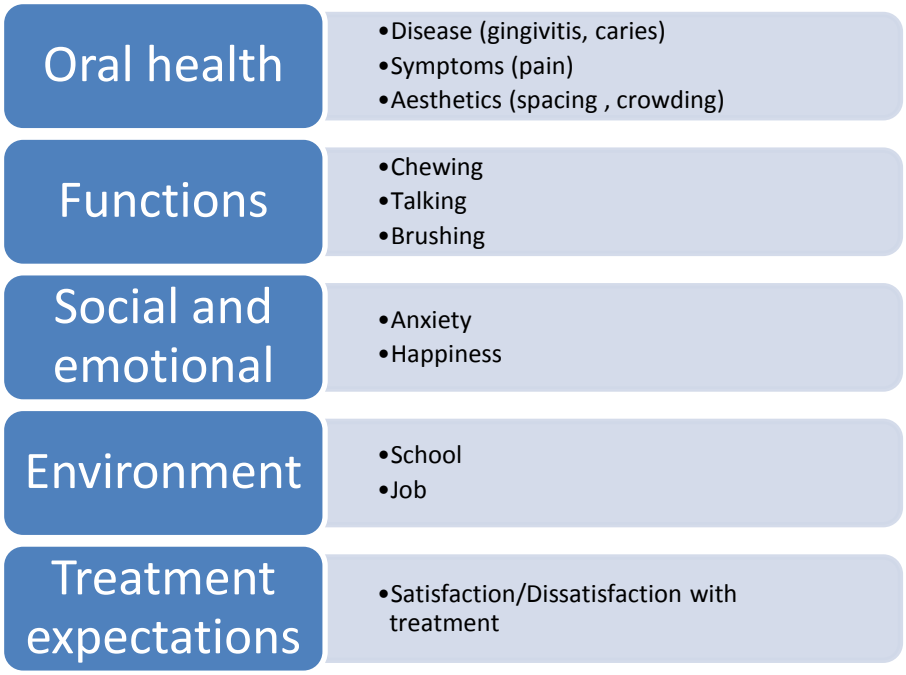


Figure 1.0-1: List of possible domains and factors in OHRQoL (adapted from Sischo and Broder, 2011)

The use of OHRQoL measures can be applied in 3 general domains: theoretical, political, and practical. It can be used to explore and evaluate various models of oral health or ascertain which factors are influential to patient's health. Furthermore, with a validated tool, it can aid in identifying priorities of the public and allocate health funds appropriately. Additionally, OHRQoL measures can be used as a clinical governance tool (clinical audit, service evaluation, and evaluation of healthcare interventions) (Gilchrist et al., 2014; Sischo and Broder, 2011).

Many measures are available for adults which look at various functional, psychological and social domains covering a variety of oral diseases and conditions. Regarding measures for children, they can be either answers by the parents as a proxy for the child, or by the child themselves, depending on the tool. It should be noted that there are differences in cognitive development between adults and children (Glichrist et al., 2014; Barbosa and Gaviao, 2008).

Children's understanding of self and health is dependent on their age. This process begins at the age of 6 years where children show signs of abstract thinking. Moreover, children begin comparing themselves with their peers and against norms in terms of appearance and personality. By 11 years of age, children have a multidimensional understanding of health and use a wide range of indicators to identify illness (Barbosa and Gaviao, 2008).

The available tools to assess children's OHRQoL are shown in Table 1.10:

Table 1.10: OHRQoL measures

Name	Authors (Year)	Validity/Reliability	Questionnaire design	Other Information
Child Perception Questionnaire (CPQ)	CPQ 8-10: Jokovic et al. (2004) CPQ 11-14: Jokovic et al. (2002)	• Variable scores in validity and reliability.	• 8-10 year old; has 25 items in 4 domains • 11-14 year old; has 37 items in 4 domains • 4 short versions based on the 11-14 year old questionnaire; 8 to 16 items in 4 domains	• Multiple translations available
Child Oral Impact on Daily Performance (C-OIDP) index	Gherunpong et al. (2004)	• Limited evidence regarding validity and reliability	• 8 items in 1 domain	• Developed from the adult version (OIPD) • Multiple translations available
Child Oral Health Impact Profile (COHIP)	COHIP: Broder et al. (2007) COHIP-SF19:	• Valid for age 8-15 • Used for caries, malocclusion and craniofacial abnormalities • Strong content and conduct validity with limited evidence of reliability	• Original has 34 items in 5 domains • Short form available. Used for children as young as 7 years; 19 items in 3 d9omains	• Designed for clinical situations • Multiple translations available •

	Broder et al. (2012)			
Early Childhood Oral Health Impact Scale (ECOHIS)	Pahel et al. (2007)	• Validity of child section compared to family section and global health rating (general and dental)	• 13 items (9 child items and 4 family items)	• Answered by parents for children age 3-5
Scale of Oral Health Outcomes for 5 yrs (SOHO-5)	Tsakos et al. (2012)	• Qualitative phase to assess content • Further research needed	• 7 item questionnaire	• Interview based questionnaire
Michigan Oral health Related Quality of Life (MOHRQoL)	Filstrup et al. (2003)	• Information lacking	• 10 item questionnaire for child version	• Answered by parents
Paediatric Oral Health Related Quality of Life (POQL)	Huntington et al. (2011)	• Content checked through piloting and focus groups • Validity checked with global oral health rating • Test-retest done to assess reliability	• 10 item with 4 domains	• Age range 2-16 during development. Parents completed questionnaire for pre-school children. Children aged 8 years and above completed their own questionnaire

1.3.2 COHIP and COHIP-SF19:

Child oral health impact profile (COHIP) was developed through a multi-stage process for research and clinical practice. It includes both positive and negative items and was initially used on paediatric and orthodontic patients, in 3 languages (English, French, and Spanish). The 34 items covered oral health, functional well-being, social/emotional well-being, school environment and self-image (Gilchrist et al., 2014; Broder et al., 2012).

The questionnaire was validated to the “Multidimensional Self Concept Scale” and “Global self-concept rating”, which looked at emotional and social aspects of the participant. Furthermore, the “Dentofacial image” scale was used to examine the participants feeling towards their facial features, and “Social Anxiety Scale” was used to evaluate the participant’s feelings of social anxiety in relation to their peer relations and interactions (Dunlow et al., 2007).

The COHIP-SF19 was developed by Broder et al., (2012). Three different populations were selected; paediatric dental patients (age 7-17 years), orthodontic patients (age 9-17 years), and patients with craniofacial anomalies (age 7-18 years). After eliminating any content overlap, COHIP-SF19 was compared to the original COHIP measure was found consistent validity and reliability. Moreover, the psychometric properties of the short version were retained (Broder et al, 2012).

1.4 Indication of Sedation Need (IOSN):

The IOSN was developed by Coulthard et al. in 2011 to be used as an indicator of the sedation need in adult patients. The purpose of the tool was to aid in clinical judgement. Coulthard et al. (2011) suggested it should be used in two settings:

1. A referral tool used within a commissioned dental service
2. A health need assessment tool

The tool assesses 3 domains; anxiety, treatment complexity and health status. Treatment complexity and health status are completed by the clinician with the anxiety evaluated using the MDAS. A total score from 3-11 is given and patients are ranked as minimal, moderate, high or very high sedation need. The authors of the tool advocate that those ranked as minimal or moderate may not need sedation, and those ranked as high or very high requiring treatment under sedation; furthermore, those scoring 9 and above may benefit from general anaesthesia. Table 1.11 was taken from Coulthard et al., (2011) and summarises the scoring of the IOSN:

Table 1.11. Summary of IOSN (Coulthard et al., 2011)

IOSN Domain	Score	Source
Anxiety	1-3	Based on MDAS score: MDAS between 5-11 is minimal anxiety, scores 1 MDAS between 12-18 is moderate anxiety, scores 2 MDAS between 19-25 is high anxiety, scores 3
Medical history	1-4	A range of medical and behavioural indicators is provided; as a general rule, ASA class is utilised: ASA I, scores 1 ASA II and/or strong gag reflex, scores 2 or 3 (depends on clinical judgment) ASA III, scores 4
Treatment Complexity	1-4	An indicative list of treatments is provided. If the user of this tool is in doubt about the complexity of any given treatment, they are asked to score high
3-4	Minimal need for sedation	No
5-6	Moderate need for sedation	No
7-9	High need for sedation	Yes
10-11	Very high need for sedation	Yes

1.4.1 Paediatric Indicator of Sedation Need (p-IOSN)

The IOSN is only used in adults as the anxiety survey used is valid only for adults; furthermore, the treatment complexity scoring was based on the treatment needs of adult patients.

Madouh and Tahmassebi (2016) developed a paediatric version of the IOSN, using a similar scoring method. However, treatment complexity was adjusted to better suit treatment need of the paediatric patient. Moreover, the anxiety surveys were divided into 2 age groups (6 to 9 years of age, and 10-16 years of age) with the use of FIS and MCDAS-*f*. The summary of the p-IOSN is shown in the methodology section (section 2.2, Table 2.2).

The authors also found that no significant association was noted between the treatment outcomes and p-IOSN scoring. Additionally, they suggested that although the tool may be helpful in predicting those patients who may benefit from treatment under sedation, further research was required to validate the p-IOSN scoring (Madouh and Tahmassebi 2016).

1.5 Aims:

- To assess the predictability outcomes of treatment under nitrous oxide/oxygen inhalation sedation of child patients referred to the sedation unit at Leeds Dental Institute (LDI) utilising the Paediatric Indicator of Sedation Need (p-IOSN) as a health needs assessment tool.
- To assess quality of life before and after sedation using the Children Oral Health Impact Profile Short form (COHIP-SF19).

1.6 Null Hypotheses:

- There is no statistically significant association between p-IOSN score and outcome of treatment.
- There is no statistically significant difference in quality of life before and after treatment.
- There is no statistically significant association between baseline quality of life and anxiety, gender, treatment complexity, sedation need and age.

Chapter 2

2.0 MATERIALS AND METHODS

The present study was carried out in two phases:

Phase 1: To assess the predictability of treatment outcomes. Baseline questionnaires were given at the assessment appointment to assess anxiety, while the clinician assessed treatment needs and medical status. Patients were followed-up and their outcomes were recorded.

Phase 2: Quality of Life assessment. Baseline quality of life assessment was carried out and for those who completed treatment as planned, 2 weeks following the last appointment, a second quality of life assessment was completed, either during a prevention appointment or by phone call.

This chapter discusses the process of ethical approval, data acquisition and statistical analyses for both phases.

2.1 Ethical Approval

Ethical approval was first sought from the Dental Research Ethics Committee (DREC) at the Leeds Dental Institute (LDI) (Appendix 1). Subsequent to the approval by DREC, ethical approval and amendments were obtained from the National Research Ethics Service (NRES) committee of Solihull in West Midlands (REC reference number: 14/WM/1019) (Appendix 2a and 2b). Following this the study received approval from the Leeds Research and Development Directorate (R&D) in order for it to be performed at the Leeds Teaching Hospital Trust (Appendix 3).

The Chief Investigator (CI: AA) made certain that the present study was carried out in full conformance with the laws and regulations of the country in which the research was

conducted and the World Medical Association Declaration of Helsinki (World Medical Association, 2008).

2.2 Phase I: Prospective Phase

This phase utilised the p-IOSN developed by Madouh and Tahmassebi (2016). The treatment outcome was obtained prospectively, and the sedation need score was calculated. A patient and parent/legal guardian information sheet (Appendices 4 & 5) were posted to patients prior to their appointments and were given a copy again at their assessment appointments. On the day of their assessment appointment, patients and their parents/legal guardians were introduced to the study by AA in the sedation clinic pictured below (Fig 2.1).

Figure 2-1 Sedation Unit at the Leeds Dental Institute

Upon their willingness to participate, the parent or legal guardian was asked to sign a consent form (Appendix 6). Similarly, the child patient was assented to participate using age appropriate forms (Appendice 7 & 8). After that, each child participant was asked to complete an anxiety questionnaire. There were two anxiety questionnaires; the FIS

(Appendix 9) was used for children under 10 years of age and the $MCDAS_f$ (Appendix 10) for children 10 years of age or older. According to the score the patients achieved on the anxiety scale, the CI calculated an “anxiety score” for each child and transferred this to the data collection sheet (Appendix 11). The following data were also transferred to the data collection sheet:

a. Age
b. Gender
c. p-IOSN : which is the sum of:
    - Anxiety score
    - Treatment complexity score
    - Medical status score

The means by which p-IOSN was calculated will be discussed below.

Inclusion criteria:

- All patients attending the sedation unit for under inhalation sedation at LDI for comprehensive dental care
- ASA class I or II patients
- Ages 7-16 years

Exclusion criteria:

- Patients referred to the sedation unit just for a single procedure (e.g. orthodontic extraction)
- Patients who are unable to communicate directly with the health care personnel who is carrying out the treatment

Calculation of p-IOSN Score

The IOSN was recently introduced by Coulthard and co-workers in 2011 (Coulthard et al., 2011). The IOSN was originally designed to be used by adult patients, however, it

was modified by Madouh and Tahmassebi (2016) in a previous study, using child appropriate anxiety measures and treatment complexity rankings (Tables 2.1 and 2.2).

Anxiety

Two anxiety scales were used as there was a wide age range of participants; the FIS was used for children aged 7- 9 years due to its ease of completion and brevity (FIS score ranged 1- 5); the scoring was ranked as following:

- FIS 1 was scored as minimal anxiety
- FIS 2-3 were scored as moderate anxiety
- FIS 4-5 were scored as high anxiety.

For participants aged 10-16years , the $MCDAS_f$ was used to evaluate their anxiety levels, with a score ranging from 8-40; the scoring was ranked as follows:

- 8-17 as minimal anxiety
- 18-28 as moderate anxiety
- 29- 40 as high anxiety.

These cut-off points used are identical to those used by Madouh & Tahmassebi (2016) in the previous study.

Treatment Complexity

The treatment complexity ranking used by Coulthard et al. (2011) was modified by Madouh & Tahmassebi (2016) to be more suitable for the child patient, and is explained in Table 2.1 below.

Table 2.1 Treatment Complexity Rank Score for the Paediatric Version of the Indicator of Sedation Need (p-IOSN)

Rank	Description	Score
Routine	Polishing, fluoride application, fissure sealants, one-surface restorations	1
Intermediate	2-surface restorations, extraction of 1 primary tooth, one-quadrant restorative dentistry	2
Complex	Crown preparation, pulp treatment, extraction of multiple primary teeth, multiple-quadrant restorative dentistry, extraction of 1 permanent tooth	3
High complexity	Multiple extractions of permanent teeth, surgical extractions, biopsy Any treatment considered more complex than above or are multiples of the above	4

Medical Status

The medical status scoring was taken from the IOSN and ranged from 1-4 depending on the ASA class:

- ASA I score of 1 on p-IOSN.
- ASA II and/or have a strong gag reflex score of 2 or 3 depending on the severity of the case.
- ASA III had a score of 4.

Table 2.2 shows a summary of the p-IOSN used.

Table 2.2 Summary of p-IOSN Scoring System

p-IOSN domain	Source	Score
Anxiety	**For 7 to 9 years old patients [Facial Image Scale (FIS)]:**	
	1 is minimal anxiety	1
	2 or 3 is moderate anxiety	2
	4 or 5 is high anxiety	3
	For 10 to 16 years old patients [Faces version of the Modified Child Dental Anxiety Scale ($MCDAS_f$)]:	
	8-17 is minimal anxiety	1
	18-28 is moderate anxiety	2
	29-40 is high anxiety	3
Treatment complexity	Routine	1
	Intermediate	2
	Complex	3
	High Complexity	4
Medical status	ASA I	1
	ASA II and/or strong gag reflex (depends on clinical judgment)	2-3
	ASA III	4

Total p-IOSN score	Anxiety score + treatment complexity score + Medical status score	3-11

Key:

p-IOSN: Paediatric Version of the Indicator of Sedation Need

ASA classification: American Society of Anesthesiologists classification of physical health

ASA I: Healthy

ASA II: Mild Systemic Disease

ASA III: Severe Systemic Disease (that does not pose a constant threat to life)

Sample Size Determination

Statistical advice was sought for the prospective phase of the study. Due to the lack of available literature, it was decided to recruit at least 40 (sample used in Madouh and Tahmassebi, 2014), with the aim of recruiting at least double (80 or more) (Appendix 12).

2.3 Phase II- Quality of Life Assessment

The COHIP-SF19 was used to assess quality of life of school-aged children. This short form of the COHIP was found to be a reliable and valid method to assess oral health-related quality of life for all school-aged children by Broder and co-authors (2012).

Calculation of Quality of Life

A 19-item questionnaire constructed by Broder and co-authors (2012) was used. The child was interviewed in the presence of their legal guardian. The questionnaire was completed initially during the assessment appointment, then 2 weeks following the final

appointment; this was carried out either in the prevention appointment, or by phone call following a verbal consent of the legal guardian.

Sample Size Determination

Statistical advice was sought and it was advised to recruit 30 participants for this part of the study. However, it was decided to assess the quality of life of all of the participants in the study.

Statistical analysis used:

- Descriptive statistics to display demographic data and frequencies
- Wilcoxon signed rank test and effect size to assess difference in baseline QoL scores and post-treatment scores
- Single and multiple linear regressions to assess predictability of baseline QoL scores against multiple variables
- Binary logistic regression to assess predictability of treatment outcomes against multiple variables
- Effect size calculated by dividing mean change in scores by the standard deviation of the pre-treatment scores,
  - Less than 0.2 indicate a small effect size
  - 0.2–0.7 a moderate effect size
  - >0.7 a large effect size

Chapter 3

3.0 RESULTS

This chapter contains the results of the two phases:

- Phase I: Prospective phase where the predictability of the treatment outcome was compared to the p-IOSN and other related factors.
- Phase II: Quality of Life assessment. Comparing scores before and after treatment and assessing predictability of baseline quality of life scores.

3.1 Phase I: Prospective Phase

Figure 3.1 summarises the recruitment of patients. The subjective assessment of patients suitability showed to have high sensitivity (48/51 = 94%), with only 3 children being referred back for treatment under local anaesthetic. Only 26 participants were rated as high sedation need. Three participants were given an outcome of “Others” as they were unable to give informed consent for treatment at the time of the assessment; requesting more time to decide on the different options that were discussed.

Figure 3.1: Flow diagram of patient recruitment

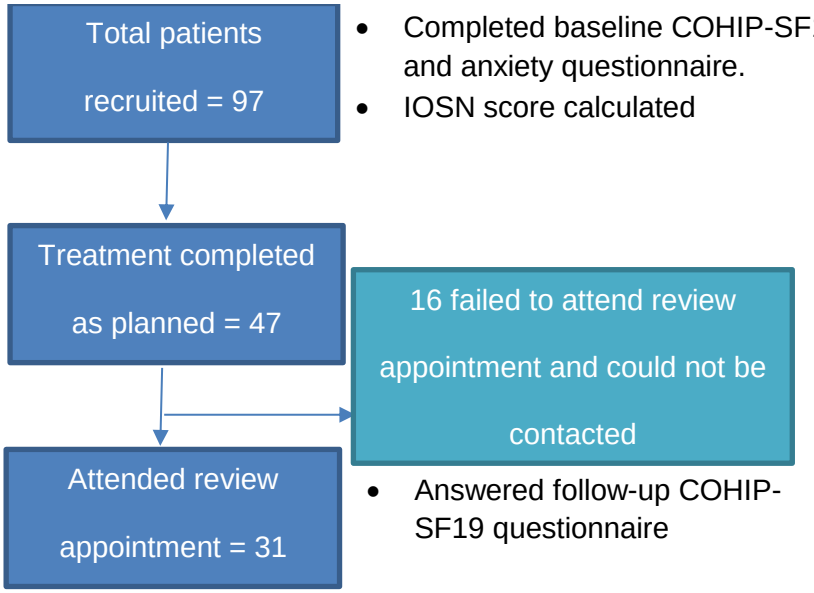


Figure 3.2: Gender distribution

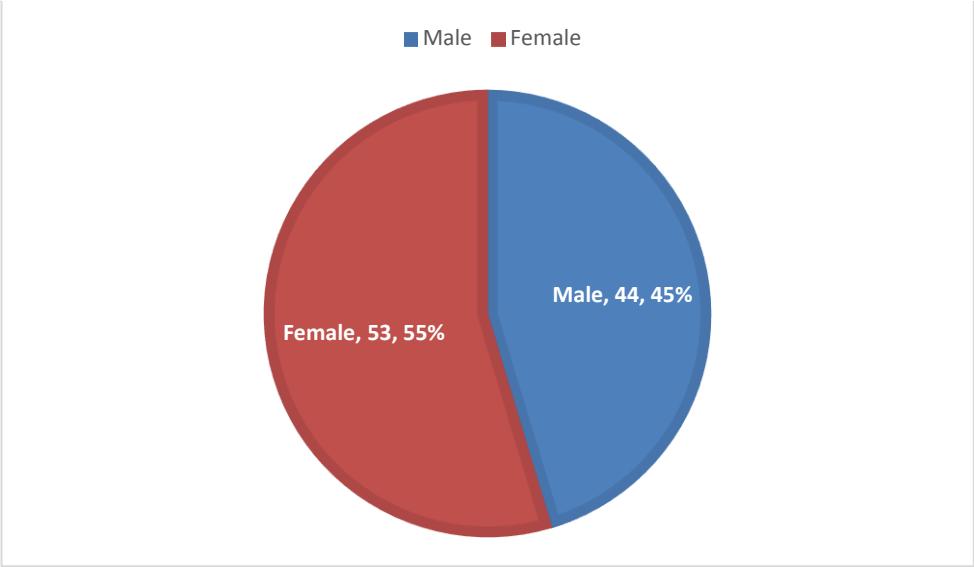


Table 3.1 Descriptive information of participants recruited in the study

Age	7-9yrs = 49	10-16yrs = 48	Range = 7-15	Mean (SD) = 10.06 (2.593)			
Anxiety	Low = 20	Moderate = 55	High = 22				
Treatment Complexity	Routine = 3	Intermediate = 9	Complex = 74	Highly complex = 11			
Medical Complexity	ASA 1= 89	ASA 2/strong gag reflex = 8					
Sedation Need	Minimal = 5	Moderate = 66	High = 26				
Outcome of treatment	Completed as planned = 47	Modified plan completed = 1	Abandoned and went to GA = 20	Abandoned and went to LA = 3	Failed to attend = 5	Others = 3	Treatment ongoing = 18

A total of 97 participants were recruited by the chief investigator. There were slightly more female patients (n=53) than male patients (n=44), with a mean age of 10.06 years (SD 2.593). The majority of the patients were of moderate anxiety (n=55/97) and needing mainly complex dental treatment (n=74/97). A large proportion of the children were ASA class I (n=89/97), and had moderate sedation needs (66/97).

Regarding the outcome of treatment, 47/97 completed treatment as planned, with 20 patients referred to treatment under general anaesthesia and a further 18 patients still undergoing care (Table 3.1).

Table 3.2 Cross tabulation of Outcome of treatment vs Various Factors

Outcome	Gender		Age		Treatment complexity				Anxiety			Sedation need		
	M	F	7-9yrs	10-11yrs	Routine	Intermediate	Complex	Highly complex	Low	Moderate	High	Minimal	Moderate	High
Completed as planned	21	26	21	26	2	8	34	3	7	31	9	3	34	10
Modified treatment completed	0	1	1	0	0	0	1	0	0	1	0	0	1	0
Treatment abandoned – referred to GA	8	12	8	12	1	1	16	2	5	7	8	1	11	8
Treatment abandoned – referred to LA	3	0	3	0	0	0	3	0	3	0	0	1	2	0
Failed to attend	4	1	3	2	0	0	4	1	0	5	0	0	3	2
Others	2	1	3	0	0	0	3	0	0	3	0	0	3	0

18 participants still undergoing treatment (n=79)

Table 3.3 Binomial Logistic Regression between "Treatment Completed" and "Treatment Abandoned- patient referred to GA"

Variable	OR	Significance	95% CI for OR	
			Lower	Upper
Low Anxiety		0.290		
Moderate Anxiety	0.280	0.116	.057	1.367
High Anxiety	436228284.128	0.999	.000	.
Routine Treatment		0.931		
Moderate Treatment	0.000	1.000	.000	.
Complex Treatment	1.902	1.000	.000	.
Highly Complex Treatment	726503931.611	1.000	.000	.
Minimal Sedation Need		1.000		
Moderate Sedation Need	0.278	1.000	.000	.
High Sedation need	0.000	1.000	.000	.
Younger age group	1.614	0.452	.463	5.624
Male	1.493	0.523	.436	5.110

3.1.1 Completed as Planned vs Referred to GA

When comparing those that completed treatment as planned against those that were referred for treatment under GA (Table 3.2) in terms of anxiety, the majority were classified as having “moderate anxiety” (34/47 vs 11/20); however, a further 8/20 participants that were referred to having treatment under GA were classified as having “high anxiety”. With regards to sedation need, 31/47 were classified as having “moderate sedation need” in the “completed as planned” group; for those participants that were referred to GA, the sedation need was variable with 8 being “high sedation need”, 7 being “moderate sedation need” and 5 being “low sedation need”.

3.1.2 Binomial Regression to Assess Predictability of Treatment Outcome

Table 3.2 above shows that for some of the variables, the sample of participants in certain outcomes are low. The majority of participants had completed the treatment as planned (47/97), followed by treatment abandoned and being referred to GA (20/97) (Table 3.1). For this reason, we have compared those two outcomes in terms of their predictability and the variables measured. A binomial logistic regression was preformed to ascertain the effects of anxiety, treatment complexity, sedation need, age group and gender on the predictability of the outcomes. There were no statistically significant associations between the treatment outcomes and the variables tested (Table 3.3).

3.1.3 Referral to General anaesthesia

As seen in Table 3.4, there were slightly more females and 11-16 year old participants referred to have treatment under general anaesthesia, with only one participant classified as “minimal sedation need”.

The most common reason for referral was anxiety (15/20). Other reasons included severe gag reflex (2/20), poor cooperation (1/20), feeling unwell after sedation (1/20), and parents feeling child would not cope with sedation (1/20). Only 4/20 of those

referred to GA were symptomatic, two of them refusing any treatment under sedation. Out of those who were referred for treatment under GA, 5/20 managed some treatment under sedation.

Table 3.4: Reasons for referral to GA and treatment needed

Age of patient (Gender)	Reason for failed Sedation	Treatment completed under Sedation	Treatment left to be completed	Symptoms present
8 yrs. (F)	Anxious about extraction, refused to accept LA	None	Restoration of 4 permanent teeth and 3 primary teeth	No
15 yrs. (M)	Complex extraction of crowned tooth	None	Extraction of 3 permanent teeth	No
12 yrs.(F)	Anxious about extractions	Restoration of 1 adult tooth	Extraction of one adult tooth	No
15 yrs. (F)	Needle phobic, not accepting Local anaesthetics	None	Extraction of 3 permanent teeth and 2 primary teeth Restoration of 1 permanent tooth	Yes
9 yrs. (M)	Very anxious patient	None	Extraction of 4 primary teeth Restoration of 4 permanent teeth and 2 primary teeth	No
8 yrs. (F)	Uncooperative patient, managed LA but cannot manage treatment	None	Extraction of 1 primary tooth Restoration of 4 primary teeth	No
9yrs (F)	Very anxious patient	None	Restorations of 4 permanent teeth and 2 primary teeth	No
11yrs (F)	Anxious about multiple extractions	None	Extractions of 4 Permanent teeth	Yes

14 yrs. (F)	Anxious about treatment, Ok with LA	Restoration of 1 adult tooth	Restoration of 1 adult tooth	Yes, on eating
11 yrs. (M)	Very anxious	None	Extraction of 6 primary teeth Restoration of 4 permanent teeth and 1 primary tooth	No
7yr (F)	Anxious and developed infection	None	Extraction of 5 primary teeth Restoration of 2 primary teeth	Yes
13 yrs. (M)	Severe Gag Reflex	Restoration of 1 permanent tooth	Restoration of 3 permanent teeth	No
13 yrs. (F)	Anxious with LA	None	Restoration of 4 permanent teeth	No
13 yrs. (F)	Very Anxious	None	Extraction of 1 permanent tooth and 2 primary teeth Restoration of 1 permanent tooth	No
7 yrs. (M)	Anxious about trying nasal hood	None	Extraction of 4 primary teeth Restoration of 2 permanent teeth and 1 primary tooth	No
11 yrs. (M)	Anxious about treatment	None	Extraction of 2 permanent teeth Restoration of 4 permanent teeth	No
7 yrs.(M)	Tried sedation, became anxious	Fissure sealing 4 teeth	Extraction of 2 primary teeth	No
14 yrs.(F)	Severe gag reflex, felt unwell with sedation	None	Restoration of 5 permanent teeth	No

8 yrs. (M)	Father feels son wont cope with sedation	None	Extraction of 4 primary teeth Restoration of 2 permanent teeth and 2 primary teeth	No
13 yrs.(F)	Very anxious regarding extraction	Extraction of 1 permanent tooth	Extraction of 1 permanent tooth	No

3.2 Phase II - Quality of Life Assessment

All of the 97 participants who were recruited in this study completed the COHIP-SF19 questionnaire. Out of those who completed the treatment under IHS as planned, a total of 31/47 (66%) completed both initial and final QoL assessment. Out of those that did not complete the questionnaire, 4 were discharged back to their GDP and chose not to attend the review appointments and another 12 participants did not attend the review appointment and none could be contacted by telephone.

Table 3.5A displays the frequency of answers for the baseline QoL assessment. It is interesting to note that In the oral health wellbeing domain, a large proportion of the participants reported to have pain in their teeth almost all the time or fairly often (73/97) prior to any dental treatment in the sedation clinic. Regarding bleeding gums and bad breath, the answers were more varied with the majority being “sometimes” for bad breath (36/97) and “almost never” (48/97) for bleeding gums.

The baseline scores in the functional wellbeing domain were largely positive, with the exception of the question “had difficulty keeping your teeth clean?” 44 out of97 participants selected “sometimes” and 31/97 participants selected “fairly often”.

Regarding the social/emotional wellbeing domain, there were variable responses to “being unhappy or sad” and “felt worried or anxious”; though the majority answered “almost never” for “being unhappy or sad” (42/97), “sometimes” and “fairly often” were selected in 78/97 of respondents. “Avoiding smiling was noted to be answered positively with more than half of the participants answering as “never” or “almost never” (55/97); however, 33 responded as “sometimes” avoiding smiling, with 1 participant responding as “almost all the time”.

A similar trend of responses was seen between “felt that you looked different” and “been worried about what people think about your teeth, mouth or face”, with the majority answering “never” (62/97 and 74/97) respectively. Though most participants answered

“never” or “almost never” with regards to bullying, 23 out of 97 did respond to this question with “fairly often” and “sometimes”. More than half of the children responded as “sometimes” missing school for any reason (64/97). With regards to “not reading and speaking out loud”, the answers were varied with 27/97 as “never”, 34/97 responding as “almost never” and 29/97 as “sometimes”. More than half of the participants responded as “almost all the time” or “fairly often” with regards to confidence and attractiveness (62/97 and 76/97 respectively).

Table 3.5A Frequency Table for baseline responses of COHIP-SH19

Domain	Scoring				
Oral Health Wellbeing	**Almost all the time**	**Fairly often**	**Sometimes**	**Almost never**	**Never**
Q1. Had pain in your tooth/teeth	**32**	**41**	**18**	**4**	**2**
Q2. Had discoloured teeth or spots on your teeth?	**---**	**---**	**11**	**37**	**49**
Q3. Had crooked teeth or spaces between your teeth?	**---**	**1**	**7**	**33**	**56**
Q4. Had bad breath?	**---**	**2**	**36**	**39**	**20**
Q5. Had bleeding gums?	**1**	**3**	**31**	**48**	**14**
Functional Wellbeing	**Almost all the time**	**Fairly often**	**Sometimes**	**Almost never**	**Never**
Q6. Had difficulty eating food you like to eat?	**---**	**2**	**17**	**42**	**36**
Q7. Had trouble sleeping?	**---**	**1**	**19**	**38**	**39**
Q8. Had difficulty saying certain words?	**---**	**---**	**---**	**16**	**81**
Q9. Had difficulty keeping your teeth clean?	**2**	**31**	**44**	**16**	**4**
Social-Emotional Wellbeing	**Almost all the time**	**Fairly often**	**Sometimes**	**Almost never**	**Never**
Q10. Been unhappy or sad?	**---**	**11**	**36**	**42**	**8**

Q11. Felt worried or anxious?	**10**	**39**	**39**	**9**	**---**
Q12. Avoided smiling or laughing?	**1**	**8**	**33**	**44**	**11**
Q13 Felt that you look different?	**---**	**3**	**3**	**30**	**62**
Q14. Been worried about what people think about your teeth, mouth or face?	**---**	**---**	**3**	**20**	**74**
Q15. Been teased, bullied, or called names by other children?	**---**	**3**	**21**	**42**	**31**
Q16. Missed school for any reason?	**1**	**16**	**64**	**14**	**2**
Q17. Not wanted to speak/read out loud in class	**2**	**5**	**29**	**34**	**27**
	Never	**Almost never**	**Sometimes**	**Fairly often**	**Almost all the time**
Q18. Been confident?	**---**	**5**	**30**	**45**	**17**
Q19. Felt that you were attractive (good looking)	**---**	**4**	**17**	**39**	**37**

3.2.1 Changes in QoL following dental treatment under inhalation sedation

It can be seen from Table 3.5B that overall, most participants responded more favourably to all three domains of the questions after the completion of treatment under IHS.

It is important to note in particular the responses to the social-emotional wellbeing domain, in particular in respect to confidence and attractiveness. There was an increase in respondents that answered “fairly often” or “almost all the time” for confidence and more participants answered “almost all the time” for attractiveness.

Table 3.5B Quality of Life scores before and after treatment (n=31)

Domain	Scoring									
Oral Health Wellbeing	**Almost all the time**		**Fairly often**		**Sometimes**		**Almost never**		**Never**	
Q1. Had pain in your tooth/teeth	**7**	**---**	**21**	**---**	**2**	**---**	**1**	**11**	**---**	**20**
Q2. Had discoloured teeth or spots on your teeth?	**---**	**---**		**---**	**4**	**---**	**12**	**4**	**7**	**27**
Q3. Had crooked teeth or spaces between your teeth?	**---**	**---**		**---**	**1**	**4**	**11**	**18**	**19**	**9**
Q4. Had bad breath?	**---**	**---**		**---**	**11**	**4**	**13**	**17**	**7**	**10**
Q5. Had bleeding gums?	**---**	**---**		**---**	**18**	**2**	**7**	**14**	**6**	**15**
Functional Wellbeing	**Almost all the time**		**Fairly often**		**Sometimes**		**Almost never**		**Never**	
Q6. Had difficulty eating food you like to eat?	**---**	**---**	**1**	**---**	**8**	**4**	**18**	**22**	**4**	**5**
Q7. Had trouble sleeping?	**---**	**---**		**1**	**7**	**4**	**19**	**21**	**5**	**5**
Q8. Had difficulty saying certain words?	**---**	**---**		**---**		**1**	**9**	**11**	**22**	**19**
Q9. Had difficulty keeping your teeth clean?	**---**	**---**	**9**	**1**	**16**	**13**	**5**	**14**	**1**	**3**
Social-Emotional Wellbeing	**Almost all the time**		**Fairly often**		**Sometimes**		**Almost never**		**Never**	

Q10. Been Unhappy or sad?	**---**	**---**		**---**	**14**	**5**	**14**	**23**	**3**	**3**
Q11. Felt worried or anxious?	**---**	**1**	**2**	**2**	**14**	**10**	**12**	**15**	**3**	**3**
Q12. Avoided smiling or laughing?	**---**	**---**	**2**	**1**	**8**	**8**	**17**	**11**	**4**	**11**
Q13 Felt that you look different?	**---**	**---**		**---**		**1**	**9**	**4**	**22**	**26**
Q14. Been worried about what people think about your teeth, mouth or face?	**---**	**---**		**---**	**1**	**1**	**5**	**4**	**23**	**26**
Q15. Been teased, bullied, or called names by other children?	**---**	**---**		**---**	**6**	**1**	**12**	**11**	**13**	**19**
Q16. Missed school for any reason?	**---**	**---**	**3**	**1**	**21**	**16**	**6**	**11**	**1**	**8**
Q17. Not wanted to speak/read out loud in class	**---**	**---**	**2**	**1**	**6**	**6**	**12**	**7**	**11**	**17**
	Never		**Almost never**		**Sometimes**		**Fairly often**		**Almost all the time**	
Q18. Been confident?	**---**	**---**	**---**	**---**	**7**	**4**	**12**	**17**	**7**	**10**
Q19. Felt that you were attractive (good looking)	**---**	**---**	**---**	**---**	**4**	**2**	**13**	**12**	**14**	**17**

*** Grey columns represent baselines scores and white columns are after treatment scores**

The mean baseline QoL score was found to be 23.14 (9.51), while following dental treatment the mean score has changed to 13.97(8.30), indicating that following treatment the total scores showed an improvement in QoL. Improvements were also seen in all 3 domains (Table 3.6A).

As the data was found not to be normally distributed, Wilcoxon signed rank test was used to calculate the significance. Though we found there to be a significant difference between baseline and post-treatment scores, and between the domains at baseline and post treatment, the effect size was large for both the total score (0.964), oral health wellbeing (1.541), and social-emotional well-being (0.849) (Table 3.6A).

Table 3.6A Quality of Life Score

COHIP-SF19	**Number**	**Mean (SD)**
Prior to Treatment	97	23.14(9.51)
Oral Health Well-being		6.67 (2.57)
Functional Well-being		3.92 (2.00)
Social-Emotional Well-being		12.49 (5.90)
After Treatment	31	13.97(8.30)
Oral Health Well-being		2.71 (1.94)
Functional Well-being		3.74 (1.90)
Social-Emotional Well-being		7.48 (5.25)

Table 3.6B Changes in Quality of Life

COHIP-SF19	Direction of change	Number	Mean Rank	Significance (SD)	Effect size
Total Score	Positive	26	18.19	0.000	0.964
	Negative	5	4.60		
	Ties	0			
Oral Health Well-being	Positive	29	15.00	.000	1.541
	Negative	0			
	Ties	2			
Functional Well-being	Positive	16	12.31	.019	0.09
	Negative	6	9.33		
	Ties	9			
Social-Emotional Well-being	Positive	21	16.57	.001	0.849
	Negative	7	8.29		
	Ties	3			

Wilcoxon signed rank test

3.2.2 Linear Regression Assessing Predictability of Baseline QoL

Single and multiple logistic regression analyses were used to assess the significance that various factors may have as a predictor of QoL. The ability of five variables (Table 3.6B) to predict baseline QoL were examined in a univariate analysis. Only changing from high anxiety to low anxiety was found to be a statistically significant predictor for QoL, with more than a 6-point improvement in QoL.

Table 3.7. Single logistic regression analysis of the predictor variables for baseline QoL

Variable	Categories	n	B	95% CI	p-Value
Anxiety	Low	20			
	Moderate	55	1.040	(-3.765)- 5.847	0.668
	High	22	6.632	0.946-12.318	0.023
Gender	Male	44			
	Female	53	-3.147	(-6.963)-0.670	0.105
Treatment Complexity	Highly complex	11			
	Complex	74	1.514	(-4.415)-7.442	0.613
	Moderate	9	3.875	(-4.821)-12.571	0.378
	Routine	2	5.500	(-6.798)-17.798	0.377
Age group	7-9 years	49			
	10-16 years	48	-2.554	(-6.372)-1.264	0.187
Sedation	High	26			
	Moderate	66	-3.716	(-8.064)-0.663	0.093
	Minimal	5	-1.131	(-10.301)-8.040	0.807

When assessing the variables independently, a statistically significant association was found between low and high anxiety levels, and a positive effect on QoL. Though the other variables were not statistically significant, as anxiety increases, QoL decreases. A similar trend was found when evaluating treatment complexity. The reverse is true for sedation need. Older age groups and being female also were shown to lead to an improved quality of life (Table 3.7).

Table 3.6 . Multiple logistic regression analysis of the predictor variables for baseline QoL

Variable	β	S.E.	B	95%CI	p-Value
Moderate Sedation Need	0.021	2.950	0.429	(-5.430) – 6.287	0.885
Minimal Sedation Need	0.077	5.041	3.291	(-6.720)-13.303	0.515
Moderate Anxiety	0.054	2.481	1.038	(-3.889)-5.966	0.677
High Anxiety	0.315	3.758	7.126	(-0.337)-14.589	0.061

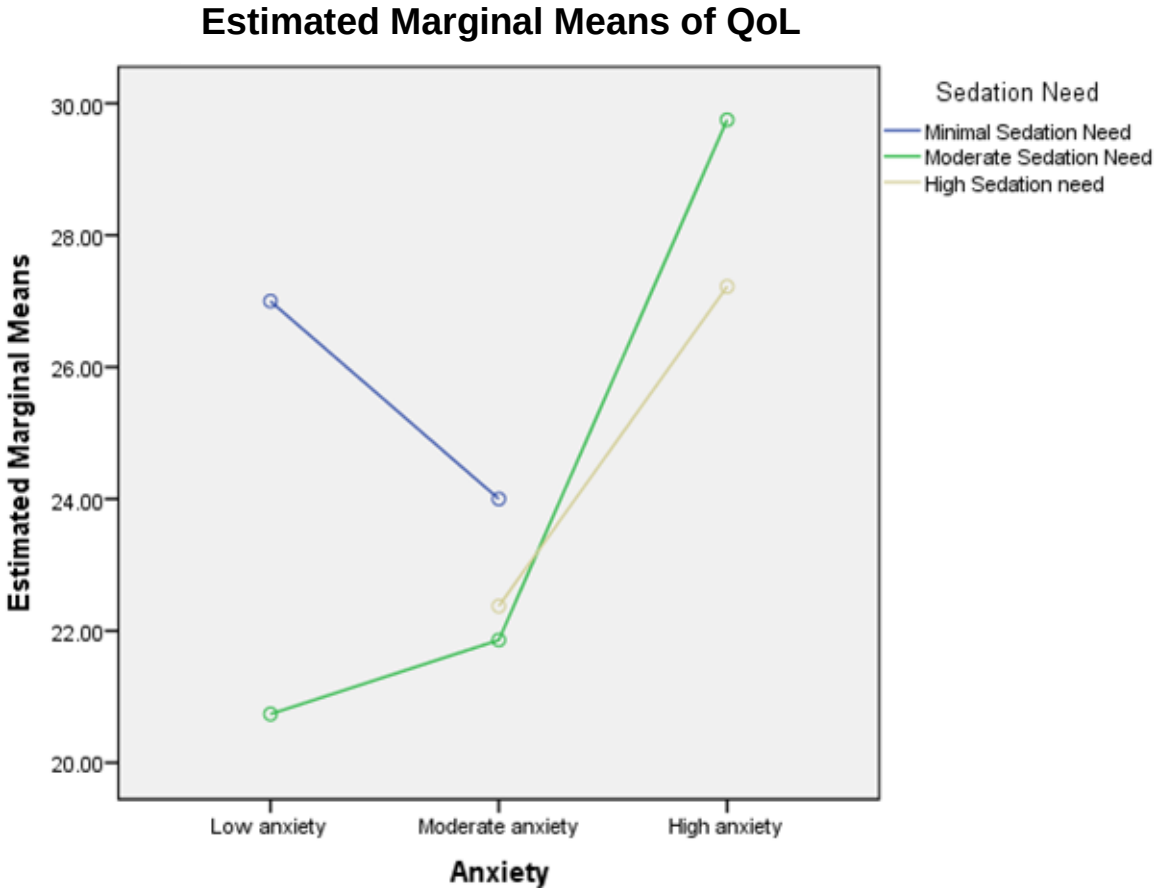
When controlling for sedation need, changing from high to low anxiety was no longer found to be statistically significant (p-Value=0.061) (Table 3.8).

It should be noted that no patients with minimal sedation were classified as having High anxiety and no patients with high sedation need were classified as having Low anxiety (Table 3.9). The plot below (Figure 3.3) illustrates that as anxiety increases, the QoL score increases (i.e. poor QoL) with moderate and high sedation need.

Table 3.7 Cross-tabulations showing Anxiety vs Sedation need

		Sedation Need		
		Minimal Sedation Need	Moderate Sedation Need	High Sedation Need
Anxiety Level	Low Anxiety	1	19	0
	Moderate Anxiety	4	43	8
	High Anxiety	0	4	26

Figure 3.3. Plot of Changes in Baseline Qol Score vs Different Levels of Anxiety and Sedation Need



Chapter 4

4.0 DISCUSSION

4.1 Methodology and Study design:

The IOSN tool was developed by Coulthard et al. (2011) to be used as either a:

1. Referral tool to aid in identifying suitable patients who may benefit from treatment under sedation (Goodwin et al., 2012); tool completed by referring dentist.
2. Health need assessment tool to assess the needs of the population and commission dental services accordingly (Pretty et al., 2011).

The IOSN is a relatively recent tool that can be used as an adjunct to clinical judgement. Though the authors produced further publications of the use of IOSN as described above, only one study investigates the use of IOSN in children (Madouh and Tahmassebi, 2016), which led to the development of the p-IOSN. With that in mind, the investigators of this current study decided to expand on the existing available evidence regarding the use of the p-IOSN.

Although the IOSN was completed by the referring dentist (Goodwin et al., 2012), the p-IOSN was completed following referral of the patient to the sedation department. The p-IOSN was used to evaluate suitability as a referral tool, expanding on the recent pilot study by Madouh and Tahmassebi (2016).

Similar methodology was used as for the study by Madouh and Tahmassebi (2016); however, the age of inclusion was adjusted to suit the quality of life measures used. The patients referred to the sedation clinic were followed-up and the outcomes were assessed. The outcome of treatment was compared to various factors incorporated in

the p-IOSN to help evaluate whether these factors could assist in predicting treatment outcome.

Though multiple OHRQoL measures are available for use, COHIP was found to have very strong positive evidence of content and construct validity (Gilchrist et al., 2014). Furthermore, a shorter version was available (COHIP-SF19), which was compared to the COHIP and global health self-rating score for validity. Additionally, the COHIP-SF19 was used for paediatric patients aged 7 years and older. Both COHIP and COHIP-SF19 have been used worldwide with multiple translations available (Gilchrist et al., 2014; Broder et al., 2012). The authors who developed COHIP-SF19 stated the time-frame it covers is 3 months (Broder et al., 2012). The investigators therefore agreed to conduct the review QoL assessment 2 weeks following their last appointment.

As COHIP-SF19 covered a large age range and is a concise tool that has been validated to previous versions (Broder et al., 2012) the investigators agreed to select this tool to assess quality of life before and after treatment.

4.1.1 Sample Size Calculation

At the time of study design, there was a lack of published articles conducting a similar study. Advice was sought from a qualified statistician at the University of Leeds who advised the following:

1. With regards to the prospective phase of this study a previously conducted study, using the p-IOSN, recruited a total of 40 patients. Therefore, it was suggested to recruit at least 40; however, the investigators of the study agreed to recruit at least double. The recruitment began in February 2015 and ended in March 2016.
2. Regarding the second phase (QoL Assessment), there was a lack of available studies conducting quality of life before and after treatment involving inhalation sedation, so it was decided to recruit at least 30 participants.

4.1.2 Strengths and limitations of study design:

The p-IOSN tool was completed at the first appointment on the sedation clinic (i.e. assessment appointment). At this stage all patients attending this appointment had been subjectively assessed by qualified dentists and consultants.

The quality of life assessment tools were answered by the children and not by the parents as proxy. Though multiple measures using the parents to evaluate their child's quality of life have been validated, the use of an age appropriate questionnaire answered by children can provide reliable and valid results (Barbosa and Gaviao, 2008). Furthermore, younger participants completed the COHIP-SF19 with the help of the lead investigator to ensure clarity of the questionnaire. Though this may lead to interview bias, it ensured that all participants understood the questions asked.

4.2: Quality of life before and after treatment under inhalation sedation

A total of 47 participants were eligible with 31 completing both before and after questionnaires; however, 4 were discharged and decided to be reviewed by their family dentist, the remaining failed to attend their appointments and could not be contacted through the provided phone numbers. Paediatric patients are dependent on their primary caregiver with respects to their oral and general health. Hallberg and co-authors (2008) conducted qualitative interviews of 12 parents to examine why they failed to bring their children to dental appointments; the overriding theme was being "overloaded in everyday life" and giving oral health low priority. Furthermore, the authors go on to mention that parents lacked dental care traditions and trust in the dental services, with some lacking parental confidence. There are local measures set up by the Leeds Teaching Hospital Trust to aid in reducing rates of missed appointments, however, clinicians should work with parents to ensure continuity of care.

This study showed that quality of life improved following completion of dental treatment under inhalation sedation; improvements were seen in total score and in the domain scores. Current published evidence only discusses changes in OHRQoL following dental treatment only under general anaesthesia, (Gaynor and Thompson, 2012; Jankauskiene and Narbutaite, 2010; Klassen et al., 2009; White et al., 2003), with no literature found on OHRQoL following completion of dental treatment under inhalation sedation.

Gaynor and Thompson (2012) used parental- caregiver perception questionnaire (P-CPQ). A total of 144 children were reviewed 1 month following their general anaesthesia. They found a statistically significant difference when comparing the change in quality both in the total score and domains (p value < 0.001). Effect size calculations showed large effect for the difference in total scores (0.88), and oral symptoms (1.22). The P-CPQ divided the emotional and social domains separately with large effect size reported for emotional domain (0.71). The authors did discuss such weakness, such as mixed method of data collection for post-operative scores, they failed to mention concerns regarding the time frame. The P-CPQ questionnaire covers a 3-months period, where the authors conducted the post-operative review only 1 months after the general anaesthesia. Though the current study used a different measure of quality of life under inhalation sedation, similar results were found. Furthermore, Barbosa and Gaviao (2008) found that parents could provide important information regarding their child's OHRQoL, however, some parents may lack knowledge in terms of social and emotional experiences.

A systematic review prepared by Jankauskiene and Narbutaite (2010) found immediate improvement in the child's quality of life was seen, with a positive impact on families. However, long term effects were not investigated. As multiple measures were used (Children OHRQOL, Francis Hospital Children OHRQoL, Dental Discomfort Questionnaire, P-CPQ, ECOHIS, interviews), they concluded that a more accurate comparison may not be possible. There is also no agreement on which measure should

be used for analysis of quality of life for children; the authors felt that there was a need to standardise the process to analyse children's OHRQoL.

Klassen and co-authors (2009) included two control groups in their study investigating changes in quality of life following treatment under general anaesthesia using ECOHIS. Their results showed that the treatment group had a significant positive change in their quality of life score when compared to the control group. Interestingly, dental fear was still present after treatment. However, the study did not compare scores within the 5 domains of the ECOHIS questionnaire, or discuss the effect size. Nonetheless, their study incorporated the use of the control group which was not done in other studies including this current study.

White and co-authors (2003) investigated changes in quality of life through a 10 item questionnaire covering 3 aspects; parental satisfaction, parental perception on the impact of GA on the child's OHRQoL in terms of physical health and social well-being. Though the paper was not clear on how the satisfaction was assessed, the parental perception on the impact of GA were assessed using closed-ended positively term statements; descriptive statistics were performed. The results did show improvement 2-4 weeks after treatment; however, the long-term effects were not investigated.

A more recently published systematic review regarding OHRQoL following dental treatment under general anaesthesia found similar findings, with the majority of the published literature using measures answered by parents as a proxy. Furthermore they reported that although overall improvements were noted, this was not always consistent in the subscales (Knapp et al., 2016).

The present study found similar results to the papers discussed above; however, the studies mentioned used parents as proxy (Gaynor and Thompson, 2011; Klassen et al., 2009; White et al., 2002); furthermore, treatment modalities varied to the current study. This study is the first of its kind to assess the impact Inhalation Sedation has on the child from the child's perspective.

4.3 Predictability of Baseline Quality of Life:

White and co-authors (2003) assessed predictors of parental perceptions of better oral health using multivariate regression. Their analysis showed that being female had a statistically significant positive effect on quality of life. Additionally, being “pain free”, “looking better”, “smiling more”, and “more social” were seen to have a similar effect. Due to the design of the questionnaire, the parents only completed a survey following dental treatment on behalf of their child. The effect of gender, though positive in the current study was not found to be statistically significant.

When not controlling for other factors, this current study found that being highly anxious had a negative effect on quality of life, this was not seen when comparing between low and moderate anxiety. After analysing the effect sedation need had on baseline quality of life, it was not significant, but was included in the multiple logistic regression as the investigators felt it was of some clinical significance. The analysis then showed that when controlling for sedation need, being highly anxious was not found to be significantly related to quality of life.

4.4 Treatment outcomes under inhalation sedation:

This study showed 48% completion of treatment (47/97 participants), with 18 participants still undergoing care; excluding those that did not have a final outcome, the percentage increased to 59% (47/79). The proportion was lower than the previously conducted pilot study (Madouh and Tahmassebi 2016) and in published literature (Elledge et al., 2007; Foley, 2005; Bryan 2002; Crawford 1990) where success of sedation was reported to be as high as 93%.

Though Elledge and authors (2007) reported 27/29 (93%) of patients referred for sedation assessment were treated successfully using conscious sedation, 10/29 (34%) were under inhalation sedation and 17/29 (59%) were under intravenous sedation. Furthermore, a retrospective assessment showed that while 19/46 (41.0%) patients

were referred for treatment using inhalation sedation, 12/46 (26%) managed to accept treatment under inhalation sedation; no information was provided regarding the success of the treatment. The current study only looked at treatment outcomes under inhalation sedation, however, the figures for success of treatment under inhalation sedation published by Elledge and authors (Elledge et al., 2007) are lower than that of the present study.

A total of 20 participants (21%) failed to complete treatment and were consequently referred for treatment under general anaesthesia; the majority failed to complete treatment due to anxiety (15/20). Failure rates reported in literature varied from as low as 3.3% (Bryan, 2002) to 12.5% (Madouh and Tahmassebi, 2016). It should be noted that despite the higher failure rate reported in this study, only 4/20 reported having symptoms with three of the participants refusing any treatment.

The findings of the current studies varied in terms of outcomes when compared to the published literature. Bryan (2002) assessed outcome of treatment under inhalation sedation, this was based on retrospective data which is prone to bias related to record keeping such as insufficient or lost data. The recruitment process in this study was prospective where patients were followed-up until an outcome was achieved or the study was completed.

Other published literature had solely focused on the completion of inhalation or referral to general anaesthesia as the outcomes; other outcomes such as modified treatment completed, referral to local anaesthesia, or failure to attend were not assessed (Shaw et al 1996; Crawford 1990). Furthermore, both Shaw et al (1996) and Crawford (1990) recruited patients who were treatment planned for minor surgeries or extractions. The current study assessed six outcomes with a seventh category for patients who at the end of the study were still undergoing treatment. Though the previous pilot study looked at five outcomes (Madouh and Tahmassebi, 2016), a sixth was added as three

participants completed the initial baseline questionnaires but asked for more time to think about other options.

4.5 Predictability of Treatment Outcomes

As this study assessed six possible outcomes against five factors, the lead investigator found multiple outcomes with low number cases (e.g. a small proportion of patients were given the outcome of modified treatment completed, referral for treatment under local anaesthesia or failed to attend). This does show that the subjective assessment carried out prior to referral to the sedation department is adequate as only 3/97 participants decided to opt out of treatment under sedation.

However, when comparing outcomes of treatment to the five factors, some data sets had a total of zero participants or answers (refer to Table 3.8; intermediate and routine treatment complexity scores). This would lead to unreliable results following statistical analysis, it was therefore decided to only compare “treatment completed as planned” with “treatment abandoned and patient referred to GA”.

The results of the current study showed no statistically significance in terms of treatment outcome and gender. Similar findings were reported by Madouh and Tahmassebi (2016), where no significant difference was found when comparing treatment outcomes against gender and p-IOSN scores. Similarly, Foley (2005) reported that when comparing gender to behaviour and outcome scores, little difference was found. Other studies failed to mention whether there was any difference when comparing gender to treatment outcomes (Hennequin et al., 2012; Soldani et al., 2010; Bryan, 2002).

With respects to age and treatment outcome, no significant difference was noted between younger and older age groups. However, Madouh and Tahmassebi (2016) reported that patients younger than 10 years of age were more likely to require GA. This was not the case in the current research where 12/20 patients referred to GA were 11 years and above. Interestingly, Foley (2005) found a statistically significant difference

when comparing the age of patients and treatment outcome with more “younger patients” unable to complete treatment under sedation.

The findings of this study showed no statistically significant difference between anxiety and treatment outcome. However, those patients that were referred for treatment under local anaesthesia (3/97) were all categorised as low anxiety. Furthermore, patients who were treated under inhalation sedation had varying levels of anxiety (majority being moderate anxiety) with those referred for treatment under general anaesthesia having almost an even distribution of anxiety levels. However, Elledge and co-authors (, 2007) found that those treated under general anaesthesia were the most anxious; this was based on the score of 2 and no statistical analysis. Likewise, Holmes and Girdler (2005) reported a statistically significant difference in anxiety scores between sedation and non-sedation groups; however, success of treatment in both groups were not discussed.

In the present study, treatment complexity and sedation need were found to not affect treatment outcome (treatment completed under inhalation sedation vs treatment abandoned and referred to GA). Contrastingly, Liu and co-authors (2013) did report that there was a statistically significant difference in the IOSN scores of the treatment modalities investigated (LA vs IV vs GA); this difference was only significant when comparing between scores of patients referred for treatment under local anaesthesia to those receiving treatment under intravenous sedation and general anaesthesia. Moreover, they reported that the more invasiveness the treatment modality, the higher the sedation need score. Though a similar methodology was followed, Liu and co-authors (2013) conducted the study on an adult population in a minor oral surgery unit, with inhalation sedation not being used. Furthermore, it is unclear how many participants completed their treatment under each modality investigated.

4.6 p-IOSN tool

The p-IOSN tool is a novel instrument that aims to aid clinical judgement and identify those patients that may benefit from sedation, similar to the IOSN tool (Madouh and Tahmassebi 2016; Coulthard, 2012; Coulthard et al., 2011). Therefore, assessing whether sedation need, and the other component of the p-IOSN (anxiety, treatment complexity and medical status), could be used as a predictor of treatment outcome.

The results of this current study mirrored that of Madouh and Tahmassebi (2016); there was no significant association between anxiety, treatment complexity, and gender when compared with treatment outcome. Furthermore, this study adds that sedation need is not a reliable predictor for treatment outcome. This may indicate that the p-IOSN requires further fine-tuning to improve its accuracy.

The available treatment modalities for children in use at LDI are as follows:

1. Treatment using non-pharmacological behaviour management techniques with/without the use of local anaesthetic
2. Treatment under inhalation sedation (mixture of oxygen/nitrous oxide gas)
3. Treatment under general anaesthesia (comprehensive dental treatment or exodontia only)
4. Intravenous sedation limited to medically fit and well children aged 12 years and above

Indications of conscious sedations as previously discussed include patients who are anxious/phobic, those with complex treatment and medical needs, and special needs patients. Regarding the patients that attend the sedation clinic, they are referred following assessment on new patient clinics by qualified dentists under the supervision of a consultant/specialist in paediatric dentistry; the majority are ASA I or ASA II, with a variety of treatment needs. Inherently, the patients may present with variable levels of anxiety and phobia.

4.6.1 Anxiety:

Two measures are used to assess anxiety in the p-IOSN as developed by Madouh and Tahmassebi (2016); FIS for 5-9 years of age and MCDAS*f* for 10-16 years of age. However, Howard and Freeman (2007) found that the addition of faces made the MCDAS*f* suitable for children as young as 5 years. Nevertheless, the aetiology of anxiety is multifactorial. Kain and co-authors (1996), conducted a prospective study where they investigated predictors of pre-operative anxiety in children. The anxiety measures utilised self-reported and independent observational measures pre-operatively, at 2 weeks, 6 months and 1 year following treatment under general anaesthesia. They concluded predictors of child anxiety include:

1. Situational anxiety of mother
2. Temperament of child
3. Age of child
4. Quality of previous medical encounters

Though Kain and co-authors (1996) only examined patients receiving “elective ambulatory surgery” under general anaesthesia, the predictors mentioned above may still be valid for dental treatment under inhalation sedation. Excluding age of the child, the remaining predictors may not be quantified easily.

Furthermore, the IOSN utilises the MDAS anxiety measure, where a score above 19 was considered as a “highly” anxious patient. The grading used by the IOSN was selected empirically by the authors (Coulthard et al., 2011). Following piloting the survey, the authors noted no statistically significant difference between moderate and highly anxious patient, with a significant difference between low and moderately anxious patients, and the low and highly anxious patients. An issue with the original IOSN tool was that though anxiety may be high, sedation need may be scored as moderate hence no sedation was required. The conclusion reached by the authors were that the anxiety scoring used did not capture all patients and a fourth rating of “very high” was added.

(Pretty et al., 2011). Similarly, with the p-IOSN, the anxiety rankings were selected arbitrarily (Madouh and Tahmassebi, 2016).

Though anxiety, fear and phobia have been used interchangeably, they are all different identities. Anxiety can be termed as a “pre-stimulus” reaction where it is associated with apprehensive anticipation of future danger, where fear is “post stimulus” where a predefined stimulus triggering the fear; phobia, on the other hand, requires a clinical diagnosis (Porritt et al., 2013; Ohman, 2008). The investigators could not find any literature relating to anxiety scores and its correlation to anxiety levels. Additionally, the FIS used in the p-IOSN only provides an immediate reflection of how the patient feels regarding dental treatment. Other surveys such as the MCDAS and CFSS-DS can help distinguish those patients who are highly anxious (Porritt et al., 2013).

While the IOSN and p-IOSN have graded anxiety from low to high/extremely high, the measures they use are only able to distinguish the extremely anxious patients (Madouh and Tahmassebi 2016; Pretty et al., 2011).

4.6.2 Medical status:

The population in this study was limited in medical complexity, as only ASA I, ASA II, or patients with gag reflex were recruited, therefore giving a maximum score of 9. No patients were given a final sedation need ranking of very high. A total of 89/97 were classified as ASA I with the remaining 8/97 classified as ASA II; those who were classified as ASA II were either asthmatic, had a drug allergy or had a gag reflex.

4.6.3 Treatment complexity

Similar results were reported by Madouh and Tahmassebi (2016), where treatment complexity was not found to be significantly associated with treatment outcome. The current study recruited a total of 97 patients, the majority of which were classified as complex treatment needs (74/97) followed by highly complex (11/97). As a tertiary

service, it may be assumed that patients being referred to the LDI have complex treatment needs.

The results paralleled that of Madouh and Tahmassebi (2016) in which treatment complexity was not associated with treatment outcome. Though in adults, treatment complexity was found to be predictor of sedation need, the published evidence using the IOSN did not look at treatment complexity alone as a predictor of treatment outcome (Liu et al., 2013).

4.6.4 Sedation need:

In both the p-IOSN and IOSN, sedation is indicated for those scoring high or very high need. The current study did not recruit any patients with very high needs as that was not achievable with the patients who attended the sedation clinic. The majority of those who completed the treatment as planned were categorised as moderate sedation need (34/47); similarly, the majority of patients that were referred to have dental treatment under general anaesthesia were classified as moderate sedation need (11/20).

Regarding sedation need, Madouh and Tahmassebi (2016) had similar results. In the adult population, however, sedation need was associated with treatment outcome; Liu and co-authors (2013) found that the IOSN could predict those that needed sedation vs those that do not where 80% of patients were identified as requiring sedation. It should be noted that the authors grouped intravenous sedation with general anaesthesia in the sedation group when comparing sedation need against treatment under local anaesthesia.

4.7 Clinical implications

What the current study showed that changing the anxiety of the child could have an impact on the OHRQoL. Clinicians can manage anxiety in various ways using both pharmacological and non-pharmacological techniques, which should be assessed on an individual basis (SDCEP 2012; British Society of Paediatric Dentistry, 2011).

Though treatment under sedation may be seen as safer and less costly than treatment under general anaesthesia, a Cochrane review published by Ashley and co-authors (2015) found that no conclusions could be drawn as there was a lack of robust evidence. Jameson and co-authors (Jameson et al., 2007) compared the cost-effectiveness of treatment provided under inhalation sedation in primary care versus treatment under general anaesthesia in tertiary care. The comparison was based on an average cost per child. The results showed that dental treatment under general anaesthesia was about 1.5 times the price of advanced conscious sedation techniques (£359.91 vs £ 245.47). Additionally, the authors also mentioned that waiting times and treatment plans were often more favourable with conscious sedation. Furthermore, Jameson and co-authors (2007) acknowledged that the population in each group may vary in terms of special needs.

Current literature on repeat general anaesthesia for day-case dental treatment at the LDI show a rate of 8.9%; oral pain and infection and irregular attendance were found to be potential predictors for repeat general anaesthetics (Kakaounaki et al., 2010). A repeat general anaesthetic can have detrimental effects in terms of cost, potential morbidity and mortality, and behaviour and emotional effects on the child (Royal College of Surgeons of England, 2008).

4.8 Future research

The information gained from this research has showed that there are potential shortcomings with the p-IOSN and with OHRQoL assessment in children. Below are suggestions for future research based on the results of the current study.

4.8.1 Sample size:

The sample size was larger in comparison to the previous pilot study (Madouh and Tahmassebi, 2016) but was limited in terms of the age range included. This was due to

the age requirements of the additional measures used as it was validated for children aged 7 years and above.

With regards to the p-IOSN tool, it may be more beneficial to be utilised on the new patient clinic prior to any judgement made as to which treatment modality will be used; patients can then be followed-up prospectively.

4.8.2 Quality of life:

The results of this current studied showed improvement in quality of life following dental treatment; however, no long-term data was collected (i.e. at 6 months, 12 months etc.)

At present there is no standardised method to assess OHRQoL. Additionally, the measure used quantifies a qualitative outcome. Future research in the use of qualitative measures may provide more in-depth analysis regarding changes in QoL and their experiences following dental treatment such as through the use of focus groups.

4.8.3 Anxiety measures:

Currently the p-IOSN utilised 2 forms of anxiety measures (FIS for children younger than 10 and MCDAS*f* for those 10 years of age and older). This study found that anxiety was not a predictor for treatment outcome. As dental anxiety, fear and phobia are all separate identities with various aetiologies, an appropriate anxiety measures is needed. Most self-reported anxiety measures have a limited focus on situation triggers of anxiety and does not consider the theoretical framework of anxiety. One such framework is “The Five Areas Model of Anxiety” which considers the following (Porritt et al., 2013):

1. Unhelpful thoughts
2. Physical symptoms
3. Unhelpful behaviours
4. Feelings
5. Situational factors (ie parental anxiety)

One such tool is the dent al fear survey (DFS), which looks at unhelpful behaviour and physical symptoms, though the other factors above are not included. However, the short dental anxiety inventory (S-DAI) does assess multiple situations, physical symptoms, behavioural and thought aspects of dental anxiety. The S-DAI has only been validated for use in the adult population (Porritt et al., 2013).

4.8.4 p-IOSN:

As mentioned previously a prospective study recruiting patients from new patient clinics may provide further beneficial information. The final p-IOSN score could then be compared with the treatment modality which was used to complete the dental treatment. Furthermore it can be used by primary care services as a referral tool to the sedation department, and analysed in a similar fashion

4.9 Limitations of Current Study

1. The participants were recruited following their assessment for suitability to have treatment performed under inhalation sedation. This may have led to sample bias. This can be corrected by recruiting patients prior to assessment during “new patient clinic sessions”.

2. The follow-up period was limited to 2 weeks following last appointment, showing only short term changed in quality of life. Ideally a longer follow-up would be needed.

3. The QoL measure used limited the patients we could recruit as it was only suitable for those aged 7-19 years. Furthermore the questionnaire also was non-specific and calculated a general OHRQoL score.

Chapter 5

5.0 CONCLUSIONS:

1. Quality of life did improve following dental treatment under IHS, with the largest effect noted in the oral health wellbeing domain.

2. Dental anxiety had a significantly negative impact on OHRQoL.

3. The factors assessed, such as anxiety, treatment complexity, age, gender and sedation need were not found to be significant predictors of treatment outcome.

Therefore, we can accept the following null hypothesis:

- There is no statistically significant association between p-IOSN score and outcome of treatment.
- There is no statistically significant association between baseline quality of life and gender, treatment complexity, sedation need and age.

We can reject the following null hypothesis

- There is no statistically significant difference in quality of life before and after treatment.
- There is no statistically significant association between baseline quality of life and anxiety.

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7.0 APPENDIX

Appendix 1: DREC approval and recommendation:

NRES Committee West Midlands - Solihull

The Old Chapel

Royal Standard Place

Nottingham

NG1 6FS

Telephone: 0115 8839436

05 June 2014

Mr Ahmed S. Altimimi

Flat 24 Bedford Chambers 18 Bedford Street

18 Bedford Street

Leeds

LS1 5PZ

Dear Mr Altimimi

Study title:	**Outcome of treatment and changes in quality of life with treatment under inhalation sedation**
REC reference:	**14/WM/1019**
IRAS project ID:	**149819**

Thank you for your application for ethical review, which was received on 03 June 2014. I can confirm that the application is valid and will be reviewed by the Proportionate Review Sub-Committee on 11 June 2014. To enable the Proportionate Review Sub Committee to provide you with a final opinion within 10 working days your application documentation will be sent to Committee members.

One of the REC members is appointed as the lead reviewer for each application reviewed by the Sub-Committee.

Please note that the lead reviewer may wish to contact you by phone or email between Monday 9 June and Wednesday 11 June to clarify any points that might be raised by members and assist the Sub-Committee in reaching a decision.

If you will not be available between these dates, you are welcome to nominate another key investigator or a representative of the study sponsor who would be able to respond to the lead reviewer's queries on your behalf. If this is your preferred option, please identify this person to us and ensure we have their contact details.

You are not required to attend a meeting of the Proportionate Review Sub-Committee.

Please do not send any further documentation or revised documentation prior to the review unless requested.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*	
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Liability and PI confirmation]	1	19 September 2013	
IRAS Checklist XML [Checklist_03062014]		03 June 2014	
IRAS Checklist XML [Checklist_04062014]		04 June 2014	
Letter from statistician [Letter from statistician]	1	03 June 2014	
Other [Data sheet]	1	28 May 2014	
Other [Prof Monty CV Summary]	1	04 June 2014	
Participant consent form [Appendix 5: Assent form (for patients 10-16 years old)]]	3	28 May 2014	
Participant consent form [Assent form for children age 7-9]	3	28 May 2014	
Participant consent form [Consent form]	1	28 May 2014	
Participant information sheet (PIS) [Parents information sheet]	2	28 May 2014	

Participant information sheet (PIS) [Appendix 2: Childâ€™s information sheet (ages 10-16)]	2	28 May 2014	
REC Application Form [REC_Form_03062014]		03 June 2014	
Research protocol or project proposal [Protocol]	6	28 May 2014	
Summary CV for Chief Investigator (CI) [Summary of CV]	1	02 June 2014	
Summary CV for supervisor (student research) [Dr Jinous CV Summary]	1	02 June 2014	
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of protocol of research]	1	02 June 2014	
Validated questionnaire [Appendix 10: Child Oral Health Impact Profile Short form (COHIP-SF19)]	1	28 May 2014	
Validated questionnaire [Appendix 8: The paediatric version of the Indicator of Sedation Need (p-IOSN)]	1	28 May 2014	
Validated questionnaire [Appendix 7: Faces version of the Modified Child Dental Anxiety Scale (MCDASf) (for 10 to 16 years old patients)]	1	28 May 2014	
Validated questionnaire [Appendix 6: Facial Image Scale (FIS) (for 7 to 9 years old patients)]	1	28 May 2014	

No changes may be made to the application before the meeting. If you envisage that changes might be required, you are advised to withdraw the application and re-submit it.

Notification of the Sub-Committee's decision

We aim to notify the outcome of the Sub-Committee review to you in writing within 10 working days from the date of receipt of a valid application.

If the Sub-Committee is unable to give an opinion because the application raises material ethical issues requiring further discussion at a full meeting of a Research Ethics Committee, your application will be referred for review to the next available meeting. We will contact you to explain the arrangements for further review and check they are convenient for you. You will be notified of the final decision within 60 days of the date on which we originally received your application. If the first available meeting date offered to you is not suitable, you may request review by another REC. In this case the 60 day clock would be stopped and restarted from the closing date for applications submitted to that REC.

R&D approval

All researchers and local research collaborators who intend to participate in this study at sites in the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland should apply to the R&D office for the relevant care organisation. A copy of the Site-Specific Information (SSI) Form should be included with the application for R&D approval. You should advise researchers and local collaborators accordingly.

The R&D approval process may take place at the same time as the ethical review. Final R&D approval will not be confirmed until after a favourable ethical opinion has been given by this Committee.

For guidance on applying for R&D approval, please contact the NHS R&D office at the lead site in the first instance. Further guidance resources for planning, setting up and conducting research in the NHS are listed at http://www.rdforum.nhs.uk. There is no requirement for separate Site-Specific Assessment as part of the ethical review of this research.

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor and to the R&D office. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/WM/1019	**Please quote this number on all correspondence**

Yours sincerely

Joanne Unsworth

REC Assistant

Email: nrescommittee.westmidlands-solihull@nhs.net

Copy to: *Ms Ann Gowing, Leeds R&D LTHT*

Appendix 2a: Ethical Approval Letter

RE-ISSUE 14 August 2014

NHS
Health Research Authority

NRES Committee West Midlands - Solihull
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839436

24 June 2014

Mr Ahmed S. Altimimi
Flat 24 Bedford Chambers 18 Bedford Street
18 Bedford Street
Leeds
LS1 5PZ

Dear Mr Altimimi

Study title:	**Outcome of treatment and changes in quality of life with treatment under inhalation sedation**
REC reference:	**14/WM/1019**
IRAS project ID:	**149819**

Thank you for your letter of 18 June 2014 responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Assistant Joanne Unsworth, nrescommittee.westmidlands-solihull@nhs.net.

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.

Conditions of the favourable opinion

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

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation

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with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

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

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

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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).

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" above).

Approved documents

The documents reviewed and approved by the Committee are:

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Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Liability and PI confirmation]	1	19 September 2013
IRAS Checklist XML [Checklist_18062014]		18 June 2014
Letter from statistician [Letter from statistician]	1	03 June 2014
Other [Data sheet]	1	28 May 2014
Other [Prof Monty CV Summary]	1	04 June 2014
Participant consent form [Appendix 5: Assent form (for patients 10-16 years old)]]	3	28 May 2014
Participant consent form [Assent form for children age 7-9]	3	28 May 2014
Participant consent form [Consent form]	1	28 May 2014
Participant information sheet (PIS) [Parents information sheet]	3	13 June 2014
Participant information sheet (PIS) [Appendix 2: Child's information sheet (ages 10-16)]	3	13 June 2014
REC Application Form [REC_Form_18062014]		18 June 2014
Research protocol or project proposal [Protocol]	7	16 June 2014
Summary CV for Chief Investigator (CI) [Summary of CV]	1	02 June 2014
Summary CV for supervisor (student research) [Dr Jinous CV Summary]	1	02 June 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of protocol of research]	1	02 June 2014
Validated questionnaire [Appendix 10: Child Oral Health Impact Profile Short form (COHIP-SF19)]	1	28 May 2014
Validated questionnaire [Appendix 8: The paediatric version of the Indicator of Sedation Need (p-IOSN)]	1	28 May 2014
Validated questionnaire [Appendix 7: Faces version of the Modified Child Dental Anxiety Scale (MCDASf) (for 10 to 16 years old patients)]	1	28 May 2014
Validated questionnaire [Appendix 6: Facial Image Scale (FIS) (for 7 to 9 years old patients)]	1	28 May 2014

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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- Notifying the end of the study

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/WM/1019	**Please quote this number on all correspondence**

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

Yours sincerely

pp.

Dr Rex J Polson
Chair

Email: nrescommittee.westmidlands-solihull@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Faculty Research Ethics and Governance Administrator*

Ms Ann Gowing, Leeds R&D LTHT

Appendix 2b: Amendment Approval

NHS
Health Research Authority

NRES Committee West Midlands - Solihull

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 8839436

09 February 2015

Mr Ahmed S. Altimimi
Flat 24 Bedford Chambers 18 Bedford Street
18 Bedford Street
Leeds
LS1 5PZ

Dear Mr Altimimi

Study title:	**Outcome of treatment and changes in quality of life with treatment under inhalation sedation**
REC reference:	**14/WM/1019**
Amendment number:	**Substantial Amendment 1**
Amendment date:	**21 January 2015**
IRAS project ID:	**149819**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Discussion

The Sub Committee queried that the amendment refers to "patients", i.e. children, but an adult will respond to the telephone call. Is this, effectively, making the study one of parents and no longer of patients?

The Sub-Committee asked would there be any issues with the telephone call – as many of the questions focused on anxiety – did they think that the children would them an accurate reply.

The Researcher confirmed that they would speak to the child only after the parent agrees. Also stating this method will only be used if the participants cannot come to their prevention appointment.

The Sub-Committee asked for clarification as some of the assessments include visual scales, and queried how will these be transcribed over the phone?

The Researcher responded that the questionnaire which will be used is only the quality of life assessment. This is the form with 19 questions and not the other forms. For that questionnaire there are no visual scales.

After these points were clarified the Sub-Committee agreed the amendment had no ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		03 December 2014
Notice of Substantial Amendment (non-CTIMP)		21 January 2015
Research protocol or project proposal		16 June 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/WM/1019:	**Please quote this number on all correspondence**

Yours sincerely

pp.

Dr Rex J Polson
Chair

E-mail: nrescommittee.westmidlands-solihull@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Anne Gowing, Leeds Teaching Hospitals Trust*
Faculty Research Ethics and Governance Administrator

NRES Committee West Midlands - Solihull

Attendance at Sub-Committee of the REC meeting on 28 January 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rex J Polson	Consultant Physician - Chair	Yes	
Dr Timothy Priest	Consultant in Pain Management - Vice Chair	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Joanne Unsworth	REC Assistant

Appendix 3: R&D approval:

The Leeds Teaching Hospitals NHS
NHS Trust

Ref: Amy Dickinson

08/01/2015

Research & Innovation
Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
LS2 9LN

Tel: 0113 392 0162
Fax: 0113 392 0146

r&d@leedsth.nhs.uk
www.leedsth.nhs.uk

Mr Ahmed Altimimi
Paediatric Dentistry
Leeds Dental Institute
Leeds
LS2 9LU

Dear Mr Ahmed Altimimi

Re: NHS Permission at LTHT for: Outcome of treatment and changes in quality of life with treatment under inhalation sedation
LTHT R&I Number: DT14/11225
REC: 14/WM/1019

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

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

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

If you have any queries about this approval please do not hesitate to contact the R&I Department on telephone 0113 392 0162.

Indemnity Arrangements

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

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

Yours sincerely

Dr D R Norfolk
Associate Director of R&I

Approved documents
The documents reviewed and approved are listed as follows:-

Document	*Version*	*Date of document*
NHS R&D Form	3.5	25.09.2014
SSI Form	3.5	24.09.2014
Directorate Approval		06.10.2014
REC Letter confirming favourable opinion		14.08.2014
Protocol	7.0	16.06.2014
Protocol *Summary/Synopsis*	1.0	02.06.2014
Participant Information Sheet *Parent/Guardian*	3.0	13.06.2014
Participant Consent Form *Parent/Guardian*	1.0	28.05.2014
Participant Information Sheet *Child aged 10 - 16*	3.0	13.06.2014
Participant Assent Form *Child aged 10 - 16*	3.0	28.05.2014
Participant Assent Form *Child aged 7 - 9*	3.0	28.05.2014
Questionnaire *Child Oral Health Impact Profile*		*Not Dated*
Questionnaire *Paediatric Indicator of Sedation Need*		*Not Dated*
Questionnaire *Modified Child Dental Anxiety Scale*		*Not Dated*
Questionnaire *Facial Image Scale*		*Not Dated*
Data Sheet	1.0	28.05.2014
Letter of Statistician		03.06.2014
Letter from Sponsor		19.09.2013

Appendix 4: Parent's information sheet [V.3]

Research Title

A research project to help dentists and health care providers to recognise people who are in need of sedation in order to carry out their dental treatment and the effect it may have on the quality of life

Introduction

You and your child are invited to take part in the above research study at Leeds Dental Institute.

Before you decide whether or not to take part, please take time to read the following information carefully in order to understand what this research is about and what your participation involves. Please feel free to discuss with other people and ask us if you wish to clarify any matters regarding this research. Taking part in the study will approximately add 5-10 minutes to your appointment.

Study Purpose

The purpose of this study is to help dentists and dental care providers to identify who are in need sedation in order to carry out their dental treatment in order to ensure that sedation is used fittingly. Additionally, we shall look at the effect of treatment under sedation on the quality of life also. This study will be funded by the Faculty of Medicine and Health, University of Leeds.

Some Questions You May Have

Why have I been chosen?

You and your child have been chosen because your child is attending their first visit in the sedation unit at Leeds Dental Institute.

Do I have to take part?

You are not obliged to participate **and this won't affect the treatment that your child is going to receive.** We will go through this information sheet and explain this study to you. A copy of the consent form shall be sent to you by post. If you decide to take part, a signed consent form is needed by the next appointment, although you are free to withdraw from the study at any time without giving a reason. If you wish to receive the summary of the results, we can send it to you by post if requested

What do I have to do?

We would like to ask your child some questions about how they feel at the moment (i.e. being at the dentist). The answer(s) to the question(s) will then be to our assessment form for the project. Afterwards, a comparison is done between your child's answers and the notes in their file. Your child would also be interviewed at the first visit, and two weeks after the last appointment to see how the treatment he/she had affected their quality of life.

What are the possible benefits of taking part?

We hope to understand more about how your child feels about the treatment and by taking part we can find out who would need sedation and recognise this earlier. Moreover, at the two week review, fluoride paste will be applied on their teeth to help strengthen them.

What will happen if I decided not to continue with the study?

You can withdraw from the study at any time; this won't affect your child's treatment in any way. Unless you ask us not to, the information already collected shall be used in the analysis.

What will happen to the result of the research?

The information will be stored safely and securely in the usual manner that all other clinical data/records are stored. Any personal data collected shall be kept confidential. Furthermore, the results of this study are intended to be used for professional doctorate research project by Ahmed Altimimi, and possibly published in Dental Journals and presented at conferences. **There will be no mention of specific individuals**.

What if I need to complain?

The normal complaints process will apply. You can have more information on the NHS Patient Advice and Liaison Service (PALS) website [http://www.pals.nhs.uk/]. You can also contact the local PALS office in Leeds; their contact details are as follows:

Telephone: 0800 0525270

Email: pals@leedspct.nhs.uk

Office Address:

Patient Advice and Liaison Service

NHS Leeds

1st floor rear

North West House

West Park Ring Road

Leeds

West Yorkshire

ENGLAND

LS16 6QG

Who is organising and funding this research?

This research is funded by the Faculty of Medicine and Health, University of Leeds.

Who reviewed this study?

The University of Leeds has reviewed the study. This study has been approved by NRES Committee West Midlands - Solihull Ethical committee.

Who can I contact for further information?

If you have further questions, you can contact Mr. Ahmed S. Altimimi or the lead supervisor, Dr Jinous Tahmassebi, through the following methods:

Mr Ahmed S. Altimimi:

Email: dnasal@leeds.ac.uk

Telephone: 07885603926

Dr Jinous Tahmassebi:

Email: J.Tahmassebi@leeds.ac.uk

Telephone: 01133433955

Thank you

Appendix 5: Child's information sheet (ages 10-16) [V.3]

Research Title

A project to help dentists and health care workers find a way to see who needs laughing gas in order to fix their teeth and the effect it may have on how you feel about your teeth.

Introduction

We are asking if you would join in a research project to find the answer to the question.

'Who needs laughing gas in order to fix their teeth and does it affect how you feel about your teeth?'

Before you decide if you want to join in, it's important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk to your family, friends, doctor or nurse if you want to.

Study Purpose

This project aims at helping dentists and dental care workers to see which people need laughing gas to have their teeth fixed. Also, the effect that laughing gas has is going to be checked.

Some Questions You May Have

Why have I been chosen?

We chose you because you are here in the clinic today to have your teeth fixed. You will help us find out who needs to have laughing gas to fix their teeth.

Do I have to take part?

No. It is up to you. We will ask you for your permission and signature on our information forms. If you decide to take part, a copy of this information sheet and your signed form to is given to you. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect how we fix your teeth.

What do I have to do?

You would need to answer some questions about how you are feeling, the answered will be compared to the work that the dentist did. Also, we would ask you to answer some questions on how you feel about your teeth at your first appointment and 2 weeks after your last appointment.

What are the benefits of taking part?

We hope to understand more about how you feel about the treatment and by taking part we can find out who are the children that need sedation and recognise this earlier. We will also be applying some special fluoride paste on your teeth at the end of the study.

What will happen if I decided not to continue with the study?

You can stop from the study at any time; this will not change your treatment in any way. Unless told not to, we will use the information already collected.

Who can I contact for further information?

If you have further questions, you can contact Mr. Ahmed S. Altimimi or the lead supervisor, Dr Jinous Tahmassebi, through the following methods:

Ahmed S. Altimimi

Email: dnasal@leeds.ac.uk

Telephone: 07885603926

Dr Jinous Tahmassebi:

Email: J.Tahmassebi@leeds.ac.uk

Telephone: 01133433955

Appendix 6: Consent form [V.1]

Patient Identification Number/Name:

Project Title:

A project to help dentists and health care workers find a way to see who needs inhalation sedation in order to fix their teeth and the effect it may have on their everyday life

Please initial the box if you agree with the statement to the left.

1	I confirm that I have read and understand the information sheet/letter explaining the above research project and I have had the opportunity to ask questions about the project.	☐
2	I understand that my participation and my child's are voluntary and that we are free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should we not wish to answer any particular question or questions, we are free to decline.	☐
3	I understand that my child's name will not be linked with the research materials, and we will not be identified or identifiable in the report or reports that result from the research.	☐
4	I agree my child's notes can be looked at by the researchers	☐
5	I agree for the data collected from our participation can be used in future research and for educating dentist and the dental team.	☐
6	I and my child agree to take part in the above research project.	☐
7	I would like to receive a simple summary of the results by post	☐

_____	_____	_____
Name of participant	Date	Signature
(*or legal representative and relationship*)		

_____	_____	_____
Lead researcher	Date	Signature

Copies:

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/pre-written script/information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be kept with the project's main documents which must be kept in a secure location.

Appendix 7: Assent form (for patients 7-9 years old) [V.3]

Can you help me with my project please? Circle one

YES / NO

Appendix 8: Assent form (for patients 10-16 years old) [V.3]

Patient Identification Number/Name:

Project Title:

A project to help dentists and health care workers find a way to see who needs laughing gas in order to fix their teeth and the effect it may have on how you feel about your teeth

Please ***circle*** all that you agree with (if you are unable to do so, your parents may help you).

Have you read (or had read to you) about this project?	Yes/No
Has somebody else explained this project to you?	Yes/No
Do you understand what this project is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Do you understand all the answers to your questions?	Yes/No
Do you understand it's OK to stop taking part at any time?	Yes/No
Are you happy to take part?	Yes/No

If <u>any</u> answers are 'No' or you do not want to take part, don't sign your name!

If you <u>do</u> want to take part, you can write your name on the next page

Name (Block Capitals): _____

Child's Signature: _____

Date: _____

Name (Block Capitals): _____

Parent/Guardian Signature: _____

Date: _____

The dentist who explained this project to you needs to sign too:

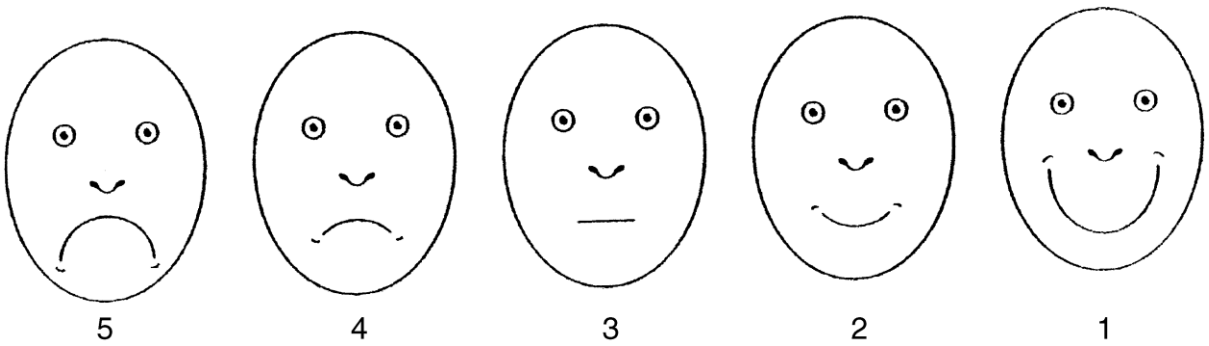
Name (Block Capitals): _____

Signature: _____

Date: _____

Appendix 9: Facial Image Scale (FIS) (for 7 to 9 years old patients) [V.1]

Please circle the “face” that is most applicable to you now:



Thank you

Appendix 10: Faces version of the Modified Child Dental Anxiety Scale ($MCDAS_f$) (for 10 to 16 years old patients) [V.1]

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

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

Please circle the most applicable number to each of the following questions:

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

Thank you

Appendix 11: The paediatric version of the Indicator of Sedation Need (p-IOSN) [V.1]

Patient serial number:		
p-IOSN domain	Possible score	Patient's Score
Anxiety	1-3	
Treatment Complexity	1-4	
Medical status	1-4	
Total p-IOSN score		
Sedation Need:		

Key:

p-IOSN metric	p-IOSN description	Sedation need?
3-4	Minimal need for sedation	No
5-6	Moderate need for sedation	No
7-9	High need for sedation	Yes
10-11	Very high need for sedation	Yes

Appendix 12: Data Collection Sheet [V.1]

		1	2	3	4	5	6	7	8	9	10	11	12	13
Personal details														
Age														
Gender (m:0, f:1)														
Patient's p-IOSN score	Anxiety score													
	Tx Complexity													
	Medical status													
	Total													
Treatment outcomes														
Completed as planned (0)														
Modified treatment completed (1)														
Tx abandoned and child referred to be treated under GA (3)														
Treatment abandoned in sedation unit and child referred to be treated under local anaesthesia (4)														
Child failed to return to complete treatment (5)														
Quality of Life score before treatment														
Quality of Life score after treatment														

Domains	Scoring				
Oral Health – Well-Being	0= Almost all the time	1= Fairly often	2= Sometimes	3= Almost never	4= Never
Q1. Had pain in your tooth/teeth?					
Q2. Had discoloured teeth or spots on your teeth?					
Q3. Had crooked teeth or spaces between your teeth?					
Q4. Had bad breath?					
Q5. Had bleeding gums					
Functional Well-Being	0= Almost all the time	1= Fairly often	2= Sometimes	3= Almost never	4= Never
Q6. Had difficulty eating food you would like to eat					
Q7. Had trouble sleeping					
Q8. Had difficulty saying certain words					
Q9. Had difficulty keeping your teeth clean					
Social-Emotional Well-Being	0= Almost all the time	1= Fairly often	2= Sometimes	3= Almost never	4= Never
Q10. Been unhappy or sad					
Q11. Felt worried or anxious					
Q12. Avoided smiling or laughing					
Q13. Felt that you looked different					

Q14. Been worried about what the people think about your teeth, mouth or face					
Q15. Been teased, bullied, or called names by other children					
Q16. Missed school for any reason					
Q17. Not wanted to speak/read out loud in class					
	0= Never	1= Almost never	2= Sometimes	3= Fairly often	4= Almost all the time
Q18. Been confident					
Q19. Felt that you were attractive (good looking)					

Appendix 13: Child Oral Health Impact Profile Short form (COHIP-SF19) [V.1]