

**Creation and evaluation of a cognitive pamphlet designed to help
children needing nitrous oxide inhalation sedation.**

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To my family, especially my mum who supports and cheers me on in everything I do.

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Declaration

This thesis represents the original work of the author.

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Synopsis

A number of paediatric dental patients are highly anxious about dental treatment and this prevents them from accepting dental treatment in the conventional manner. There are a number of techniques available to help subjects deal better with treatment and one of the more commonly used techniques is nitrous oxide inhalation sedation. This technique involves the administration of a titrated mixture of nitrous oxide and oxygen through a nose-piece with the aim of sedating a patient to a point where s/he can cope with dental treatment. This technique is highly successful but it still requires a certain amount of cooperation on the part of the patient. Some patients find it hard to accept the nose-piece while others accept it initially but then still do not manage to relax enough for dental treatment to be carried out. Children's coping strategies vary and are dependent on factors such as age, personal characteristics and cultural influences. Research shows that cognitively oriented coping strategies are more constructive in the dental setting and it is possible to teach children how to use such strategies. Preparation for surgery and anaesthesia is clearly important and many children consider the dental visit a stressful situation. Cognitive behaviour therapy has been used to help subjects cope with various medical conditions and also in preparation for surgery.

The aim of this project was to develop and evaluate a cognitive pamphlet to help facilitate inhalation sedation treatment for anxious paediatric dental patients. The project was carried out in three parts.

The first study, a retrospective case note review of the patients undergoing inhalation sedation at Glasgow Dental Hospital and School, ascertained the population sample.

The case notes of all the patients who attended for dental treatment with inhalation sedation at the Glasgow Dental Hospital in the year 2005 were pulled and demographic details of the patients were recorded from them. The results showed that the mean age of the patients attending was 10.8years with a range of 5 to 16 years and about 53% of patients were female. Therefore, it was concluded that the pamphlet should target children aged between 7 and 16 years and it should be equally appealing to both genders.

In the second study a cognitive pamphlet was designed, evaluated qualitatively and modified. The pamphlet was designed by the main researcher with the help of a psychologist. It consisted of a three-panel brochure with bold colourful images and text. It presented the subject with three sets of cognitive exercises to practice at home and perform during treatment. The pamphlet was qualitatively evaluated by a focus group of paediatric dentists using a structured interview questionnaire. The pamphlet was then amended according to the suggestions of the interviewees.

The third study was a single blind randomised controlled clinical evaluation of this modified pamphlet.

Subjects were assessed and recruited to the study from the sedation assessment clinics in the Glasgow Dental Hospital and the Community Dental Services. The subjects were randomly allocated to either a control or a study group. The subjects in the study group received a previously developed pamphlet consisting of cognitive behavioural therapy exercise. The children were instructed to read the pamphlet and practice the exercises at home and then use them at their first treatment visit. The preoperative anxiety levels of the subjects were assessed prior to assignment into the

respective groups. The blinded operators were asked to assess the overall behaviour of the subjects on a Global Rating Scale and a Visual Analog Scale. All the subjects had their first treatment visit videotaped and all the tapes were watched by two blinded observers at the end of the study and the subjects' acceptance of the nose-piece as well as their overall behaviour was scored. The scales used by the blinded observers were the Houpt Scale, the Visual Analog Scale and the Global Rating Scale. These scales were applied at specific time-points, namely: 1. introduction to the nose-piece, 2. fitting of the nose-piece, 3. breathing in and out of the nose-piece and 4. start of the operative procedure.

The final number of subjects participating in the study was 35, of which 11 (31.5%) were recruited from the Community Dental Services. Eighteen (51.4%) were male and the mean age was 10.2 years (7-14). Thirteen (34.2%) were in the highest level of social deprivation. The preoperative anxiety scores were very similar for both groups and the mean values (24.6 and 24.9) were higher than the normative value.

The primary outcome measure of the study was whether the pamphlet improved subject acceptance of the nose-piece. Only one subject from the control group refused to wear the nose-piece while all the subjects in the study group accepted the nose-piece. The difference was not statistically significant (Chi square test, $p = 0.324$). The secondary outcome measure was the overall behaviour of the subjects during treatment. Although, there was poor agreement between the observers, the individual results from each observer as well as the result at the time of best agreement show that there was no statistically significant difference between the two groups (Mann-Whitney and Fisher's Exact test). The results show that the pamphlet was not

successful to either help subjects accept the nose-piece or improve their behaviour during treatment.

There could be various reasons for the failure of the pamphlet to improve patient cooperation. These include an already highly successful technique (inhalation sedation), a small study sample, failure to comply with instructions to read the pamphlet, difficulty in processing cognitive exercises without the help of a psychologist and the Hawthorne effect. Although it is not possible to recommend the use a cognitive pamphlet prior to inhalation sedation at this stage, it may be possible to further investigate this idea in a future study taking into consideration the shortcomings of the present study and improving them.

Chapter 1

Literature Review

1.1 DENTAL ANXIETY IN CHILDREN

Anxiety is a commonly encountered problem in dentistry, which creates challenges for the dental team. Some patients suffer from such extreme anxiety that they avoid dental examination and treatment altogether. However, avoidance of dental treatment will exacerbate dental problems that will then require extensive treatment and this might in its turn increase anxiety.

1.1.1 *Aetiology*

The aetiology of dental anxiety is a much debated subject and a variety of theories have been put forward. One theory states that there are two groups of dentally anxious individuals; exogenous, where dental anxiety is the result of conditioning via traumatic dental experiences or vicarious learning and endogenous, where the individual has a constitutional vulnerability to anxiety disorders, as evidenced by general anxiety states (Weiner and Sheehan, 1990).

The age of origin of dental anxiety has also been extensively researched. The most commonly held view is that dental anxiety is a fear originating in childhood which persists later in life (Locker D *et al*, 1999). However, some studies have addressed this issue and challenged this view. Ost (1987) found that almost 20% of dental phobics reported onset after the age of 14. Similarly, Milgrom *et al* (1988), in a population based study, found that 33.3% became anxious during adolescence and adulthood. In a later population-based study, it was reported that only one half of the subjects claimed becoming dentally anxious in childhood; one-fifth reported adolescent onset and almost one-third became dentally anxious in adulthood (Locker *et al*, 1999).

The nature of the dental anxiety is thought to be related to the age of onset. It is believed that child-onset subjects are more likely to be exogenous, while later-onset individuals are more likely to be endogenous (Locker *et al*, 1999). A relation between invasive dental experiences and level of dental fear has been reported by Townend *et al* (2000) and Ten Berge *et al* (2002). Children with a longer history of non-invasive visits are likely to be less anxious than children who have experienced invasive dental treatment early in their dental history (Townend *et al*, 2000; Ten Berge *et al*, 2002).

1.1.2 Prevalence

Dental anxiety affects people of all ages and from all backgrounds. However, not everyone is affected in the same way and a lot depends on cultural and social influences. Studies have shown a variation among countries with regards to the prevalence of childhood dental anxiety. Worldwide studies have quoted figures ranging from 3 to 43% (Folayan *et al*, 2004). A prevalence of 7.1% was reported in Scotland (Bedi *et al*, 1992) while the range for the USA was between 6% and 10.5% (Morgan *et al*, 1980; Gatchel, 1989).

1.1.3 How dental anxiety challenges dental care

As mentioned earlier, dental anxiety poses a challenge to dental care. It is not only more difficult for the dental team to provide good treatment for a patient who is dentally anxious and therefore likely to exhibit behaviour management problems, but patients are also more likely to avoid dental treatment resulting in poor oral health. It has been shown that adults experiencing high levels of dental anxiety are among those with the poorest oral health-related quality of life in Britain (McGrath and Bedi, 2004). Furthermore, dental pathology has been found to be higher in anxious

children (Townend *et al*, 2000). Klingberg *et al* (1995) have shown that dental fear in children is associated with, and may lead to, not only the avoidance of dental care but also more carious tooth surfaces and behaviour management problems. This can have implications on treatment planning and treatment for these patients. Goumans *et al* (2004) reported that, dentally anxious children with or without behaviour management problems have similar treatment plans in terms of dental treatment performed and time required. However, anxious children with behaviour management problems were more often treated with nitrous oxide inhalation sedation compared with behaviour management techniques or general anaesthesia (Goumans *et al*, 2004).

Therefore, dental anxiety is a significant problem in dentistry. For this reason, various management techniques have been developed to try making the provision of dental treatment easier and more pleasant for patients. Techniques adapted to help patients include hypnosis, sedation and general anaesthesia for those patients who either lack co-operation or are severely phobic.

1.2 NITROUS OXIDE INHALATION SEDATION

One of the most commonly used sedation techniques to help dentally anxious individuals cope better with dental treatment is nitrous oxide inhalation sedation.

Horace Wells originally demonstrated the anaesthetic properties of nitrous oxide in 1844. More recently, nitrous oxide has been adapted for use as a sedative rather than a general anaesthetic agent. The discovery and early trials of nitrous oxide were motivated by a need to control pain and anxiety in patients. This same reason accounts for the current popularity of this sedative technique (Duncan and Moore, 1984).

1.2.1 *What is Nitrous oxide Inhalation Sedation?*

During inhalation sedation, nitrous oxide is delivered to the patient in a very specific manner to induce relaxation and enhance co-operation with the dental team. The technique involves the administration of a titrated mixture of nitrous oxide and oxygen via a nose-piece, to which appropriate scavenging equipment is attached. Sedation is combined with behaviour management and dental treatment is carried out, usually using local anaesthesia, whilst maintaining verbal contact throughout the procedure (Lyratzopoulos and Blain, 2003). At the end of the visit, patients are allowed to breath 100% oxygen for 2-5 minutes to completely eliminate the nitrous oxide from their system (Holroyd and Roberts, 2000) before they are discharged.

Nitrous oxide inhalation sedation is not a new sedation technique. In fact, it has been used as a patient management technique in UK dentistry since the 1940s (Shepherd and Hill, 2000). During this time, the possible adverse effects have been researched extensively and it has been reported that the nitrous oxide inhalation sedation has an extremely low incidence of patient morbidity (Jastak and Paravecchio, 1975; Roberts

et al. 1979; Duncan and Moore, 1984). Adverse reactions associated with the use of nitrous oxide are infrequent, especially when it is administered to healthy patients and combined with at least 50% oxygen (Duncan and Moore, 1984). The side effects that have been most commonly associated with inhalation sedation include nausea, vomiting and headache (Duncan and Moore, 1984; Shepherd and Hill, 2000).

Nitrous oxide inhalation sedation is mainly indicated in healthy, mild to moderately anxious individuals who are willing and able to co-operate with the requirement of wearing a nose-piece. The main contra-indications to this technique are the very severely phobic and the pre-co-operative individuals. Medical contra-indications to nitrous oxide inhalation sedation are few and include; the common cold, tonsillitis, nasal blockage, bleomycin chemotherapy and the first trimester of pregnancy (Hosey, 2002).

1.2.2 *How common is the use of Nitrous Oxide in the UK and worldwide?*

There is currently not much information to tell us how commonly nitrous oxide inhalation sedation is used as a behaviour management technique either in the UK or in the rest of the world. The Poswillo report (1990) recommended that alternatives to general anaesthesia should be sought and indicated that inhalation sedation was the most appropriate alternative for children. Following this report, studies, such as the audit carried out by Jones *et al* in 1998, have concentrated on finding out whether the use of general anaesthesia in dental practice has decreased rather than whether the use of sedation has increased (Whiston *et al*, 1998). In the UK, there have only been three studies that reported how commonly sedation is being used in general practice. The first study was carried out in Glasgow by Blinkhorn *et al* (1992) and it was shown that only 14% of respondents claimed to use inhalation sedation. The next

study carried out in 1996, to examine the use of general anaesthesia and sedation among general dental practitioners in two Scottish health boards, has shown that only 9% of practitioners were using inhalation sedation (Macpherson and Binnie, 1996). The most recent study available was published in 1998 and showed that only 8% and 16% of practitioners from two districts in Northern England were using inhalation sedation (Whiston *et al*, 1998).

A later paper published in 2002 reported the use of nitrous oxide inhalation sedation among specialist paediatric dentists and general practitioners in Israel. It was shown that 97% of specialists and 28% of non-specialists reported the use of inhalation sedation (Peretz, 2002). Regulations in the UK recommend that practitioners should not use a combination of drugs to induce sedation for dental treatment. However, this is not the case in the USA and therefore nitrous oxide is commonly used in combination with other anaesthetic agents for dental sedation. In fact, a 15-year follow-up survey among paediatric dentists has shown that, with regard to the use of nitrous oxide alone, 47% of practitioners responded that they use nitrous oxide alone less than 11% of the time (Haupt, 2002). Over the 15 years of the survey (1985-2000), there seemed to be a slight decrease in the use of nitrous oxide inhalation sedation (Haupt, 2002).

Therefore, it is evident from the available literature, that nitrous oxide inhalation sedation is not commonly used in general practice in the UK. It is highly likely that inhalation sedation is more commonly used in the specialist setting, mainly in dental hospitals and community dental service since it is easier to provide training facilities in these settings. However, once again, there is a paucity of literature as to how commonly nitrous oxide inhalation sedation is being used in these specialist centres.

1.2.3 *Efficacy of nitrous oxide inhalation sedation*

The success of the technique is dependent both on careful patient assessment and selection and on the operator exhibiting good behaviour management techniques. Nitrous oxide inhalation sedation is most successful when used for patients who exhibit mild to moderate dental anxiety (Hosey, 2002). The success of the technique depends on a calm, relaxed patient, breathing in an orderly way through an unblocked nose whilst listening to the reassuring and comforting words of the dentist and nurse, who help to create the necessary ambience and mood in the surgery (Crawford, 1990).

Various studies have documented the success of nitrous oxide inhalation sedation for the provision of dental treatment especially for dental extractions, most commonly for orthodontic reasons. Blain and Hill (1998) compared the efficacy of nitrous oxide inhalation sedation with that of general anaesthesia for dental extractions. They found that the success rate for completion of treatment under inhalation sedation was significantly poorer than that of general anaesthesia. However, it should be noted that the success rate for nitrous oxide inhalation sedation was still good at 83%. The patients who successfully had dental treatment with nitrous oxide inhalation sedation represented 57% of those initially referred for treatment under general anaesthesia, confirming that with careful patient selection and management, inhalation sedation can be a successful alternative to general anaesthesia extractions (Blain and Hill, 1998). Shaw *et al* (1996) reported a 90% success rate for dental extractions and minor oral surgical procedures carried out under inhalation sedation for patients who had been specifically referred for treatment under general anaesthesia. In this study the parents of patients who had previously undergone dental treatment under general anaesthesia stated that they preferred nitrous oxide inhalation sedation (Shaw *et al*,

1996). In a comparative study assessing the successful completion of orthodontic dental extractions under nitrous oxide inhalation sedation versus general anaesthetic, it was shown that sedation was successful in 96.7% of times compared to 100% for general anaesthetic (Shepherd and Hill 2000).

The age range of the subjects reported in the above studies could have been a factor in the success rate reported. In the Blain and Hill study (1998), where a success rate of 83% was reported the mean age of the patients was 7.63 +/- 2.45yrs. Shaw *et al* (1996), in their descriptive study, reported a success rate of 90% but in this case the subject ages ranged from 4 to 17 years with the majority of patients lying in the 8-13 year-old bracket. Finally, Shepherd and Hill (2000) reported a 96.7% success rate and the mean age of their patient cohort was 11.9 +/-1.78 years. So it can be seen that better success rates have been achieved with the older patient age groups. Only the study by Shepherd and Hill (2000) assessed pre-operative anxiety levels and they reported similar anxiety levels in the inhalation sedation and general anaesthetic groups.

Even though, the use of inhalation sedation has been most extensively reported for the provision of dental extractions; a few studies have also reported the successful use of inhalation sedation for completion of comprehensive dental treatment. Hallonsten *et al* (1983) reported the successful use of nitrous oxide inhalation sedation for the provision of restorations, endodontic therapy and dental extractions for children aged between 3 and 16 years. In a study carried out in a community dental clinic, Bryan (2002) has shown that, in 83.9% of cases dental treatment, which included dental restorations and extractions, was carried out as planned for anxious children with an average age of 7.2 years. In a more recent retrospective survey, it was shown that

84% of children referred for comprehensive dental treatment under inhalation sedation managed to have their treatment completed while the remaining 16% required referral for treatment using other pharmacological techniques (Naudi *et al*, 2006). The mean age of the patients treated in this study was 9.8 years.

Nitrous oxide inhalation sedation requires a certain level of co-operation and for this reason it is not as successful in very young patients and those with severe learning delay (Holroyd and Roberts, 2000). It is also of less value in those requiring multiple extractions and those who are irregular attenders (Hosey, 2002).

1.2.4 Acceptance of the nose-piece

As mentioned earlier, during inhalation sedation, nitrous oxide and oxygen are delivered to the patient via a nose-piece. Although most children usually manage to accept the nose-piece, some extremely anxious children may refuse to wear it (Hosey, 2002). In a study carried out in 1978, Cooper *et al* found that one out of the 24 patients, admitted to the trial, refused to wear the nose-piece and treatment was carried out under conventional local anaesthesia. Major *et al* (1981) found that 6 out of 40 patients (15%) refused the nose-piece and treatment with nitrous oxide inhalation sedation had to be aborted. A later study showed that 23.5% of children rejected the nose-piece in preference to local anaesthesia alone (Warren *et al*, 1983). The most recent papers (Shaw *et al*, 1996; Blain and Hill, 1998; Shepherd and Hill 2000) on the subject give percentages of failure for inhalation sedation; however they make no reference to acceptance or refusal of the nose-piece. A previous study carried out at the Glasgow Dental Hospital and School reported a rate of refusal of the nose-piece of 11% (Naudi *et al*, 2006).

Therefore, it is evident that, although nitrous oxide inhalation sedation can be a very successful behaviour management technique, it is still not appropriate for some children. In fact, studies show that some children might find it difficult to cope with accepting the nose-piece and others might accept the piece but still find it difficult to relax enough for provision of dental treatment. In view of this, it might prove beneficial for the dental team and the patient if we were to teach our paediatric patients some skills, which might help them to cope better with dental treatment facilitated by inhalation sedation.

1.3 COPING STRATEGIES IN CHILDREN

1.3.1 *Definition*

Coping consists of the “constantly changing cognitive and behavioural efforts to manage external and/or internal demands that are appraised as taxing or exceeding the resources of the person” (Lazarus and Folkman, 1984). This means that coping is the human nature’s way of trying to deal with problems and situations that cause stress and conflict. Humans have developed a variety of coping mechanisms and the use of these strategies depends heavily on personal constitution, social and cultural influences.

1.3.2 *Studies with adults*

Researchers have tried to qualify and quantify the coping strategies used by people and many studies have involved adults. These studies have not only tried to classify the coping mechanisms used in everyday life situations but also the relationship between such coping mechanisms and adjustment. Research regarding child coping mechanisms is not as extensive; however, inferences about children’s coping processes during dental treatment may be drawn from adult studies (Curry *et al*, 1988).

Folkman and Lazarus (1980) identified two types of coping strategies; problem-focused and emotion-focused, used by individuals to cope with various life-stressors. Both types were used in nearly every stressful situation but the nature of the situation played a major role in determining the response used. Problem-focused coping strategies, including seeking information and inhibiting action, were most often used when individuals felt that something constructive could be done to effect change, an example being work-situations. On the other hand, emotion-focused coping strategies

were more useful in situations when circumstances needed to be accepted or tolerated as in health or death situations.

Perlin and Schooler (1978) found that cognitive or perceptual responses that function to “control the meaning of the problem” were the most commonly used coping responses among their adult study subjects. The authors concluded that many stressful situations in life do not permit direct intervention and that the variety of coping responses used by any one person was a better predictor of adjustment than the use of any particular strategy alone.

Based on this research, one can infer that silent coping strategies (emotion-focused) would tend to be the most effective for children in the dental setting, a situation that does not allow much opportunity to effect change. Furthermore, one can also infer that children who have a varied repertoire of coping behaviours may do better than those who limit themselves to a single strategy (Curry *et al*, 1988).

1.3.3 Types of spontaneous coping strategies in children

A child’s ability to cope does seem to, at least partly; determine the emotional nature of the dental visit (Versloot *et al*, 2004). This is due to the fact that often a child who is able to cope with dental treatment is usually better behaved than a child who has no coping ability. Better behaviour tends to make dental management easier for both the child and the dental team thus resulting in a less emotionally taxing experience for all the parties involved.

Research looking into the coping strategies exhibited by children has shown that children tend to use two main coping strategies to deal with stressors; behavioural and

cognitive. Behavioural coping efforts are very apparent to the dentist and usually include overt physical or verbal activities such as refusing to open one's mouth or trying to get out of the dental chair. On the other hand, cognitive coping mechanisms tend to be silent or covert and are not usually readily apparent to the dentist. These efforts involve manipulation of one's thoughts or emotions such as when the child thinks reassuring thoughts (Curry *et al*, 1988).

Cognitive coping efforts, although silent and often unnoticed, may play a major role in the child's ability to deal successfully with dental treatment, and to generate a lasting positive impression of dental treatment (Curry *et al*, 1988). It may therefore, be of benefit for children who lack coping behaviour to learn cognitive coping skills which can help them to deal with the stress generated by dental treatment. Furthermore, it would be highly beneficial for both the child and the dental team if children, who mainly exhibit behavioural coping efforts, which tend to be disruptive, could be taught cognitive coping skills.

The various behaviour and cognitive coping strategies used by 30 children aged 8 to 10 years old were identified, using exploratory interviews and observations during restorative dental treatment (Curry and Russ, 1985). The coping techniques were stratified into various categories and their effect on adjustment was quantified. The results of this study further support the theory that cognitive coping skills are better for managing the stress related to the dental situation.

Three categories of behavioural coping were identified:

- information-seeking (gain information by asking questions and watching vigilantly)

- support-seeking (verbal and physical contact with the dentist or nurse)
- direct efforts to maintain control (attempts to participate actively in the treatment process or to set limits)

Behavioural coping strategies were related to poor outcome of adjustment to the dental situation.

Five categories of cognitive coping strategies were identified:

- reality-oriented working through (realistic and accurate thoughts about dental procedures)
- cognitive reappraisal (attempts to reduce the aversiveness of the situation via attention to positive features and avoidance or denial)
- emotions-regulating cognitions (self-statements or thoughts to alleviate fear or discomfort)
- behaviour-regulating cognitions (self-statements or thought attempting to control behaviour during treatment)
- diversionary thinking (attempt to divert thoughts away from the dental situation)

The cognitive coping strategies were found to be significant predictors of adjustment. The greater the number and variety of cognitive coping processes used the better was the adjustment to the dental situation by the child (Curry and Russ, 1985).

1.3.4 *Factors affecting coping strategies in dentally anxious children*

An individual's ability to cope with stressful situations will largely depend on personal constitution, social and cultural influences. However, other factors may affect the coping strategies that children use to deal with dental anxiety. The two mostly recognised influencing factors are age and previous experience.

1.3.4.1 Age

Interest in the field of child development began early in the 20th-century and tended to focus on abnormal behaviour. Traditionally cognitive and psychological development has been described in stages and a number of cognitive development theories including those by Freud, Erikson and Piaget have been brought forward. The theories proposed by Sigmund Freud stressed the importance of childhood events and experiences, but almost exclusively focus on mental disorders rather than normal functioning. According to Freud, child development is described as a series of 'psychosexual stages.' Each stage involves the satisfaction of a libidinal desire and can later play a role in adult personality.

Theorist Erik Erikson also proposed a stage theory of development, but his theory encompassed development throughout the human lifespan. Erikson believed that each stage of development is focused on overcoming a conflict. Success or failure in dealing with conflicts can impact overall functioning. Jean Piaget suggested that children think differently than adults and proposed a stage theory of cognitive development. He was the first to note that children play an active role in gaining knowledge of the world. It is now recognised that developmental stages are not as clear-cut as these theories propose however, for ease of clarity, development is still described in stages usually related to age groups.

- Birth to 4 years

Children aged between birth and 4 years of age are usually considered as pre-cooperative since they lack the ability to understand what is required of them and therefore are unlikely to be able to demonstrate coping skills when faced with stressful situations. This group of children is therefore not usually included in studies

researching co-operative behaviour exhibited by children in dealing with pain in either the medical or the dental situation. This might also be the reason why this age group is very rarely included in inhalation sedation studies.

- 4 to 7 years

In their review of the literature Branson *et al* (1988) concluded that the coping strategies that children used to cope with pain varied with age. The younger child (4-7 years) usually uses behaviour orientated coping strategies.

- 8 to 10 years

In the same study Branson *et al* (1988) showed that as children grow older (8-10 years), they start to supplement, but not replace, behaviour coping strategies with an increasing repertoire of cognitive coping strategies.

- 11 to 18 years

Finally, the older children (11-18 years) tend to use more cognitively orientated strategies and demonstrate more self-control when dealing with a stressor (Branson *et al*, 1988).

This conclusion was also confirmed for the dental setting in a study conducted by Van Meurs *et al* (2005) whose aim was to assess how children dealt with pain during dental treatment. The study showed that younger children (8-10 year-olds) use different coping strategies when compared to older children receiving dental treatment. Younger children tended to use more behavioural coping strategies that offered emotional support such as holding the nurse's hand or having friends around.

1.3.4.2 Dental fear and pain experience

The way that we cope with stressful and conflicting situations in life can also be influenced by previous experience. Research has shown this statement to be true in the case of the paediatric dental patient attending for treatment.

Versloot *et al* (2004) concluded that the use and choice of coping strategies of 11-year old children seems to be partly determined by their level of dental fear and their pain experience. In this study, the subjects used a variety of coping strategies, which could be classified into three groups; destructive, external and internal. The least used strategies were the destructive type, which were also the least helpful for treatment and included strategies such as closing their mouth or trying to get out of the dental chair. The external strategies were the next most often used and these included holding the nurse's hand. The children often rated these strategies as effective. The most commonly used strategies were the internal or cognitive-oriented strategies and these strategies were again rated by the children to be effective.

In this same study, it was shown that fearful children use more coping strategies and more frequently use externally focused coping strategies than children who are less fearful. This suggests that fearful children lack personal resources for managing pain and depend on the skill of their parents and professional staff to teach them and enhance their coping skills (Versloot *et al*, 2004).

Similar results were obtained in a later study conducted with 8-13 year old children (Van Meurs *et al*, 2005). The more dentally anxious children, who also had a higher frequency of dental pain experiences, showed a higher propensity to use behaviour (destructive) coping mechanisms (Van Meurs *et al*, 2005).

Therefore, research seems to show that the younger child and the child who has had negative past experiences with dentistry, making them more anxious, lack the ability to use cognitive coping mechanisms. Since this type of coping skills are the most helpful to the child and the dental team, it can be concluded that, if at all possible, paediatric dental patients should be taught such coping strategies. Learning to cope may be especially helpful since it provides individuals with skills they can use in coping with anxiety associated with dental treatment (Del Gaudio and Nevid, 1991).

1.3.5 Teaching children to cope

Children's reactions to painful procedures are thought to be mediated by their cognitive-developmental level, previous experience, perceived control over the experience, parental support and their coping style (Franck and Jones, 2003).

Despite the growing evidence base on the effectiveness of cognitive behavioural coping techniques in reducing children's pain and distress associated with medical and dental procedures, children in most healthcare settings are not being taught coping techniques (Franck and Jones, 2003). There has been research done in both the medical and dental settings which documents attempts to teach children how to cope with a variety of procedures. However, it is not clear if these techniques, most of which have been shown to be useful, are actually being used in healthcare settings after the study had been completed.

1.3.5.1 Teaching coping skills in the medical setting

Most of the research relating to teaching children how to cope with pain has been carried out in the medical setting.

In a pilot study, carried out in 2003, 6-12 year old children were taught coping techniques using a self-administered computer-based programme to deal with the pain and distress caused by venepuncture (Franck and Jones, 2003). The majority of the children reported that the programme helped them cope better with the pain of the procedure but only a minority reported that it helped them with the distress. Furthermore, all the children except one stated that they would use the programme again to help them when having venepuncture. The majority of parents were happy with the results achieved by the programme and said that they would encourage their children to use it again (Franck and Jones, 2003).

Another computer package program was evaluated in a randomised control trial carried out with children undergoing general anaesthesia for dental extractions (Campbell *et al*, 2005). Children were placed into three preparation groups; the computer package which explained the general anaesthesia experience in an interactive manner, a cartoon strip or verbal preparation only (control). The computer preparation package was significantly better at reducing anxiety and distress than the control at induction and significantly better at reducing anxiety and distress than the cartoon at recovery (Campbell *et al*, 2005).

1.3.5.2 Teaching coping skills in the dental setting

In dentistry, teaching children how to cope has not been as extensively researched as in medicine. This might be because, teaching coping skills is viewed as more of a technique related to psychology rather than dentistry. However, some researchers have looked into this area and the results achieved are very promising.

In a study carried out with pre-school children, the effectiveness in stress reduction of teaching specific coping skills or providing sensory information was investigated (Siegel and Peterson, 1980). The subjects were divided into three groups; a coping skills group, a sensory information group and a control group. The children in the coping skills group were taught general body relaxation, deep and regular breathing, pairing of relaxing cue words, the use of pleasant imagery and to use self-calming talk with phrases such as “I will be all right in just a little while”. On the other hand, the sensory information group was presented with basic information as to what to expect in the dental session. Finally, the control group was read a chapter from a storybook. The results indicate that children in both experimental groups were less anxious and distressed and were more co-operative than children in the control group (Siegel and Peterson, 1980).

Del Gaudio and Nevid (1991) conducted a study with five groups of children (mean age 11.2 years) experiencing different coping strategies and one control group with no assigned coping strategy. The study showed that the dentally phobic children who received either an exposure-based multicomponent treatment program (combining coping skills training in the dental surgery with videotape modelling) or exposure-based coping skills training (coping skills training in the dental surgery without videotape modelling), reported significantly less state anxiety than did all other treatment and control conditions (Del Gaudio and Nevid, 1991). The other treatment groups involved video modelling (subjects watched a video in the classroom but did not receive any coping skills); non-exposure based coping skills training (subjects received coping skills training in a classroom setting rather than a dental setting); information dissemination (exposure to information audiotape and discussion with a therapist but no training in coping skills) and waiting list control.

In conclusion, from all the available literature, it can be deduced that children use a variety of strategies to cope with dental treatment and that coping behaviour is influenced by personality, age and past experiences. Furthermore, it is also obvious that cognitively oriented coping strategies are more constructive in the dental situation and that it is possible to teach children how to use such strategies.

1.4 COGNITIVE BEHAVIOUR THERAPY

1.4.1 *Definition*

Cognitive Behaviour Therapy (CBT) is a term used to describe psychotherapeutic interventions that aim to reduce psychological distress and maladaptive behaviour by altering cognitive processes (Kaplan *et al* 1995). Cognitive behaviour therapy is based on the idea that one's thoughts, feelings and actions all interact together. Specifically, thoughts determine feelings and behaviour. Therefore, negative thoughts can cause distress and result in behavioural problems.

The goal of CBT is to increase self-awareness, facilitate better self-understanding and to improve self-control by developing more appropriate cognitive and behavioural skills. Cognitive behaviour therapy helps to identify dysfunctional thoughts and beliefs that are negative or biased or self-critical and seeks to replace these with more positive, balanced and functional thoughts that acknowledge strengths and successes (Stallard, 2002).

1.4.2 *CBT with children and adolescents*

There is a growing interest in the use of CBT with children and young people. This interest stems from systematic reviews, which have concluded that CBT has an effective role in the management of child psychology disorders.

A literature review carried out by Kazdin and Weisz (1998) has shown that CBT has shown promising results in the treatment of internalising and externalising childhood disorders as well as preparation for medical and dental procedures.

1.4.2.1 CBT with children under 12 years

Cognitive behaviour therapy has been used in the children under 12 years of age. However, the degree to which these children have the required level of cognitive maturity to be able to participate fully has been the subject of debate (Stallard, 2002).

A meta-analysis of cognitive behaviour therapy, with children under the age of 13 years, conducted by Durlak *et al* (1991) concluded that although all children (5-13 years) benefited from CBT, younger children (5-10 years) benefited less. However, it was not clear whether this was due to these children being too cognitively immature to engage with the CBT tasks or because the intervention was not being pitched at the right level.

Ronen (1992) suggested that adapting and matching the concepts and techniques of CBT to the developmental level of the child might help to overcome some of the developmental issues. Cognitive behaviour therapy needs to be pitched at the right cognitive developmental level to be of any effect for younger children. Therefore, the techniques used need to be concrete with clear and simple instructions (Stallard, 2002).

1.4.2.2 CBT with adolescents

Adolescents are often self-centred and they have difficulty seeing and accepting the views of others. It is often better to accept and acknowledge their views rather than directly challenging their egocentricity. This will convey the positive message that their views are being heard and respected. Failing to do this might result in the development of an oppositional stance with the adolescent feeling under pressure to define his/her views (Stallard, 2002).

1.4.3 Parental involvement

Studies have shown that the participation of parents may be beneficial. In a randomised controlled trial published in 1999, Mendlowitz *et al* concluded that cognitive-behavioural group interventions reduce symptoms of anxiety and depression in school-age children with anxiety disorders. Children whose parents participated used more active coping strategies post-treatment than the controls. These parents also reported a greater improvement in their child's well being (Mendlowitz *et al*, 1999).

The role that the parent is going to take in the CBT program needs to be agreed at the outset. There are three roles that a parent can play (Stallard, 2002):

- i. The *facilitator* acts to aid transfer of clinical skills from the clinical session to home, encouraging the child to practice new skills and tasks at home.
- ii. The *co-therapist* adopts a more active role, whereby the parent prompts, monitors and reviews the child's use of cognitive skills. In both these situations, the child remains the focus of the intervention and the parents work to reduce the child's psychological distress.
- iii. The final role is that of a *client* where the parents learn new skills or how to cope with their own problems. In this way, the parent and child can form an expert team and be able to deal with their problems

1.4.4 Examples of CBT in the medical setting

Cognitive behaviour therapy is widely used to treat a variety of medical conditions alone or in conjunction with pharmacological therapy. There is a good evidence base in terms of the effectiveness of CBT in reducing symptoms and preventing relapse. It has been clinically demonstrated in a large number of studies to be effective for many

psychiatric disorders and medical problems for both children and adolescents (Sanders *et al*, 1994; Kendall *et al*, 1994; Robins *et al*, 2005). Furthermore, it has been recommended in the UK by the National Institute for Health and Clinical Excellence as a treatment of choice for a number of mental health difficulties, including post-traumatic stress disorder, obsessive compulsive disorder, bulimia nervosa and clinical depression.

1.4.4.1 Chronic pain

Young people frequently experience and report pain but a minority subsequently become patients who report significant pain and pain-associated distress and disability (Eccleston C *et al*, 2002). The most common locations for pain are the head, limbs and gut. Chronic pain has been found to be reported more often by older children and females (Eccleston C *et al*, 2002). Older children with chronic pain often suffer of chronic disability and emotional stress due to the recurrent and persistent pain (Bursch *et al*, 1998).

In a Cochrane systematic review, Eccleston *et al* (2003) concluded that there is very good evidence to show that psychological treatments, mainly relaxation and cognitive behavioural therapy, are effective in reducing the severity and frequency of chronic headache in young people.

In a controlled clinical trial, involving 7-14 year old children with chronic abdominal pain, Sanders *et al* (1994) showed that cognitive behavioural family intervention was superior to standard paediatric care in terms of complete elimination of pain, levels of relapse, levels of interference with daily activities as a result of pain and parental satisfaction. A more recent randomised controlled trial also investigated the effects

of CBT on abdominal pain (Robins *et al*, 2005). In this study, 69 children aged between 6 and 16 years were randomly allocated to one of two treatment groups; family CBT and standard medical care or standard medical care alone. The results showed that children and their parents in the experimental group reported significantly less abdominal pain up to one year following treatment and less school absence compared to controls (Robins *et al*, 2005).

1.4.4.2 Depressive disorders

One of the most common problems encountered in child psychiatric clinics are depressive disorders (Harrington *et al*, 1998). These disorders tend to result in a range of unpleasant outcomes including social impairment, suicidal tendencies, long term effects on cognitive development and they have a high risk of recurrence (Harrington *et al*, 1998).

The pharmacological treatment of depressive disorders has included tricyclic antidepressants and selective serotonin re-uptake inhibitors (SSRI). However, a Cochrane review looking at the efficacy of tricyclic antidepressants in children and adolescents has shown that these drugs are not beneficial in pre-pubertal children and have uncertain benefits in adolescents (Hazell *et al*, 2002). The results with SSRI were equivocal in that, one study showed benefit (Emslie *et al*, 1997) and the other did not (Simeon *et al*, 1990). Furthermore, there are concerns that the benefits of certain SSRIs in treating depression do not outweigh the risks associated with their use amongst patients less than 18 years of age. Therefore, there has been a growing interest in psychological treatments particularly cognitive behaviour therapy.

Harrington *et al* (1998) conducted a systematic review of the efficacy of cognitive behaviour therapies in childhood and adolescent depressive disorders. They included six small randomised controlled trials, which treated children, aged between 6 and 18 years, exhibiting depressive disorders. Their conclusions suggest that cognitive behaviour therapy may be of benefit for mild to moderate depressive disorders in young people.

1.4.4.3 Anxiety disorders

Anxiety disorders are among most common psychiatric disorders of childhood, with an incidence of 5-18% of all children and adolescents (Soler *et al*, 2005). Anxiety disorders have a negative impact on academic, social and personal functioning (Pine, 1997). Furthermore, anxiety disorders in childhood often persist into adulthood and are associated with depression, drug abuse and suicidal tendencies (Cartwright-Hatton *et al*, 2004). These factors highlight the need for effective and readily accessible treatments for such disorders (Soler *et al*, 2005).

The pharmacological treatment of anxiety disorders is mainly selective serotonin reuptake inhibitors. As mentioned earlier, there has been recent debate over the safety of these drugs when used in children. Therefore, as with the case of depressive disorders, psychological treatments are becoming an increasingly important option for treating young people with anxiety disorders (James *et al*, 2005).

The first reported trial looking at CBT for the treatment of anxiety disorders in children was conducted by Kendall in 1994. Children, aged 9-13 years, with anxiety disorders were assigned to either a 16-session cognitive-behavioural treatment or a waiting-list condition. The results of this trial showed that CBT had positive effects.

A systematic review conducted by Cartwright-Hatton *et al* (2004) included randomised controlled trials which compared the efficacy of CBT for treatment of anxiety disorders with no treatment or inactive treatment in patients younger than 18 years. Ten trials were found to meet the inclusion criteria and the results indicate that CBT is an effective intervention for anxiety disorders of childhood and adolescence when compared to no treatment (Cartwright-Hatton *et al*, 2004) Table 1.1.

The results were confirmed by a more recently published Cochrane systematic review (James *et al*, 2005). In this case thirteen studies met the inclusion criteria and these involved young people aged 19 years or younger, treated in a community or outpatient setting who exhibited mild to moderately severe anxiety disorders. The remission rate for CBT was 56% as compared to 28.2% waiting list controls. Therefore, the conclusions were that CBT is a potentially useful treatment for anxiety disorders in children and adolescents (James *et al*, 2005) Table 1.2.

Table 1.1 Studies included in systematic review (Cartwright-Hatton *et al* 2004)

Study	Sample details	Therapy type/duration	Comparison condition	Outcome measure
Haywood <i>et al</i> (2000)	Age: 15.8 (\pm 1.6) yrs Primary diagnosis: SP	GCBT 16x1.5 hrs	No treatment	ADIS
Barrett <i>et al</i> (1996)	Age: 7-14yrs Primary diagnosis: OAD, SAD,SP	ICBT 12x60-80 min ICBT + FCBT 12x60-80 m	Wait list	ADIS-C ADIS-P
Flannery-Schroeder & Kendall (2000)	Age: 8-14 yrs Primary diagnosis: GAD, SAD, SP	GCBT 18x90 min ICBT 18x50-60 min Some parental advice given	Wait list	ADIS-IV-C ADIS-IV-P
Kendall <i>et al</i> (1997)	Age: 9-13 yrs Primary diagnosis: OAD/GAD, AD/SP, SAD	ICBT 18x60	Wait list	ADIS
Kendall (1994)	Age: 9-13 yrs Primary diagnosis: OAD, SAD, AD	ICBT 17x50-60 min	Wait list	ADIS-P
Silverman <i>et al</i> (1999)	Age: 6-16 yrs Primary diagnosis: OAD, GAD, SP	FGCBT Children 12x55 min Parents 12x55 min	Wait list	ADIS-C ADIS-P

Dadds <i>et al</i> (1997)	Age: 7-14 yrs Primary diagnosis: any DSM-IV anxiety diagnosis	FGCBT 10 x1-2 hrs Parents 3 sessions	Control schools	ADIS-P
Barrett (1998)	Age: 7-14 yrs Primary diagnosis: OAD, SAD, SP	GCBT 12 x 2hrs FGCBT 12x2hrs	Wait list	ADIS
Spence <i>et al</i> (2000)	Age: 7-14 yrs Primary diagnosis: social anxiety	GCBT 14x90 min FGCBT Children 14x90 min Parents 14x90 min	Wait list	ADIS-C-P
Shortt <i>et al</i> (2001)	Age: 6.5-10 yrs Primary diagnosis: SAD, GAD, SP	FGCBT Children 12x50-60 min Parents 6hrs	Wait list	DISCAP

GCBT= group cognitive behavioural therapy ICBT= individual cognitive behavioural therapy FGCBT= group cognitive behavioural therapy with significant family component

SP= social phobia OAD=over-anxious disorder SAD= social anxiety disorder GAD= generalised anxiety disorder AD= avoidant disorder

ADIS = anxiety disorders interview schedule ADIS-C= anxiety disorders interview schedule-children ADIS-P= anxiety disorders interview

schedule-parents DISCAP= diagnostic interview schedule for children, adolescents and parents

Table 1.2 Studies included in cochrane review (Soler *et al* 2005)

Study	Sample details	Therapy type/duration	Comparison condition	Outcome measure
Barrett <i>et al</i> (1996)	Age: 7-14yrs Primary diagnosis: OAD, SAD, SP	ICBT 12x60-80 min ICBT + FCBT 12x60-80 m	Wait list	ADIS-C ADIS-P
Barrett (1998)	Age: 7-14 yrs Primary diagnosis: OAD, SAD, SP	GCBT 12 x 2hrs FGCBT 12x2hrs	Wait list	ADIS
Dadds <i>et al</i> (1997)	Age: 7-14 yrs Primary diagnosis: any DSM-IV anxiety diagnosis	FGCBT 10 x1-2 hrs Parents 3 sessions	Control schools	ADIS-P
Flannery-Schroeder & Kendall (2000)	Age: 8-14 yrs Primary diagnosis: GAD, SAD, SP	GCBT 18x90 min ICBT 18x50-60 min Some parental advice given	Wait list	ADIS-IV-C ADIS-IV-P
Ginsburg (2000)	Age: 14-17 yrs Primary diagnosis: DSM-IV anxiety diagnosis	School based GCBT 10x45 min	Alternative control	ADIS-IV-C ADIS-CIR
Haywood <i>et al</i> (2000)	Age: 15.8 (\pm 1.6) yrs Primary diagnosis: SP	GCBT 16x1.5 hrs	No treatment	ADIS

Kendall (1994)	Age: 9-13 yrs Primary diagnosis: OAD, SAD, AD	ICBT 17x50-60 min	Wait list	ADIS-P
Kendall <i>et al</i> (1997)	Age: 9-13 yrs Primary diagnosis: OAD/GAD, AD/SP, SAD	ICBT 18x60	Wait list	ADIS
Nauta (2003)	Age: 11 yrs (mean) Primary diagnosis: GAD, SAD, SP, PAD	ICBT 12 sessions ICBT 12 sessions + FCBT 7 sessions	Wait list	ADIS-C ADIS-P
Shortt <i>et al</i> (2001)	Age: 6.5-10 yrs Primary diagnosis: SAD, GAD, SP	FGCBT Children 12x50-60 min Parents 6hrs	Wait list	DISCAP
Silverman <i>et al</i> (1999)	Age: 6-16 yrs Primary diagnosis: OAD, GAD, SP	FGCBT Children 12x55 min Parents 12x55 min	Wait list	ADIS-C ADIS-P
Spence (2000)	Age: 7-14 yrs Primary diagnosis: SP	GCBT 14x90 min FGCBT Children 14x90 min Parents 14x90 min	Wait list	ADIS-P

1.4.5 CBT in the dental setting

As is the case for coping skills, the use of cognitive behaviour therapy has not been as extensively researched in the dental setting as it has been in the medicine. Furthermore, the available research is mostly based on the adult rather than the paediatric dental population.

A randomised controlled trial conducted with a sample of 112 fearful adult dental patients compared the effects of applied relaxation to those of cognitive behaviour therapy (Berggren *et al*, 2000). In this study, patients were divided into two groups: one group was trained in muscular relaxation, which they were encouraged to practice at home; subjects in the other group were helped to identify faulty thoughts regarding dentistry, and to replace them with constructive thoughts. Both groups were then shown a sequence of video-recorded dental scenes with which the patients had to deal either by relaxation or by discussion with the therapist depending on their experimental group. The results showed that more patients in the cognitively oriented group completed treatment. However, relaxation-oriented therapy generally resulted in a more significant reduction in dental fear on the Dental Anxiety Scale and the Dental Fear Survey, as well as general anxiety and fear assessed by State-Trait Anxiety Inventory and the Geer Fear Scale (Berggren *et al*, 2000).

In 2001 Willumsen *et al* reported the immediate short-term results of a randomised controlled trial comparing cognitive therapy, applied relaxation and nitrous oxide sedation in the treatment of dental fear. They found that all three modalities of treatment were associated with significant improvements in dental fear and dental treatment progression. They then went on to review the patients and report the one-year follow-up findings (Willumsen *et al*, 2001) and reported that all three treatments

had remained effective. However, the patients in the applied relaxation group had the most favourable results. Nevertheless, this was also the method that required the most input from the patient because it had to be practised at home. The five-year follow-up results of this randomised controlled trial were further reported in 2003. All the patients treated earlier were sent out a questionnaire to assess dental fear, general distress and the use of dental services 5 years post treatment. The response rate was 69.4%. The authors concluded that all the three methods seemed to have positive effects on both dental fear and general distress after 5 years. Furthermore, it seems that the patients in the applied relaxation and the cognitive behaviour therapy groups also gained a more responsible attitude towards their oral health and dental attendance when compared to the patients in the nitrous oxide inhalation group (Willumsen *et al*, 2003).

In a pilot study with anxious paediatric dental patients, Weinstein *et al* (2003) tested a brief video intervention package to test the child's need for control in the dental situation. The study was held in a school setting and the children were randomly assigned to either watch a commercial video unrelated to dentistry or a video of a child having local anaesthesia. In the video the child patient was instructed to use a hand signal to show the dentist that he/she was experiencing discomfort. Questionnaires to assess the children's fear were distributed before and after the video intervention. The results showed that the video intervention package seemed to have had a positive effect in reducing the fear of injection pain. Furthermore, the more highly fearful children seemed to benefit more from the intervention than children with low fear levels (Weinstein *et al*, 2003).

These studies show that patients benefit from being taught relaxation and positive thinking techniques to cope with the stress caused by dental treatment. Paediatric patients also seem to benefit from receiving information about techniques and knowing that they have some control over the dental situation.

1.4.6 *Preparing children for surgery*

A child's admission to hospital is often a difficult and unpleasant experience for both the child and the family (Bar-Mor, 1997). In 1966, Vernon *et al* concluded that the negative effects of hospitalisation on children can be summarised into five categories; regression, separation anxiety, sleep anxiety, eating disturbance and aggression. Therefore, it would seem obvious that children and their parents would benefit from some sort of preparation before admission for surgical procedures.

Behavioural preparation programs for children undergoing surgery and anaesthesia have been researched and these have been shown to reduce anxiety and improve coping (Kain *et al*, 1998). Furthermore, a systematic review concluded that children and their parents require preoperative preparation before a surgical experience (O'Conner-Von, 2000). Bates and Broome (1986) reported that, according to the literature, there is a wide variety of preoperative preparation programs available but the ones most commonly reported are: hospital tours, play therapy, and filmed modelling.

The type of preparation programmes available and their content has changed significantly over the years. In the early 1960's, the emphasis was primarily on providing information and establishing trust between the child and the hospital staff. This shifted towards modelling preparation programs in the mid-1970s and was

further expanded in the late 1980s to include child-life preparation, involvement of the parents and teaching of coping and relaxation skills (Kain *et al*, 1998).

O'Byrne *et al* (1997) conducted a survey among American hospitals focusing on whether research findings were being implemented in preparation programs as compared to an earlier survey. They concluded that there had indeed been an increase in the use of techniques validated by research such as modelling and the teaching of coping and relaxation skills (O'Byrne *et al*, 1997). Furthermore, most hospitals were using preparation programs for the majority of children undergoing surgery (O'Byrne *et al*, 1997). However, despite research documenting the usefulness of filmed models, only half of the paediatric hospitals use this preparation method. Moreover, even though there is a lack of evidence to support the effectiveness of hospital tours, this method of preparation was still being used by 87% of the hospitals surveyed (O'Byrne *et al*, 1997).

The same survey reported that a panel of experts had concluded that the teaching of coping skills was the most effective intervention while no preparation at all was the least effective (O'Byrne *et al*, 1997).

In a randomised controlled trial, Kain *et al* (1998), attempted to compare the effectiveness of three preparation programs: (i) a solely information-based program, (ii) an information coupled with modelling-based program; and (iii) an information, modelling and coping-based program. The children who received the most intensive preparation program showed less anxiety not only immediately after the behavioural intervention, and later in the holding area on the day of surgery but also on separation from their parents to go to the operating theatre. These findings only reached

statistical significance in the holding area on the day of surgery and there was also no difference between the groups during induction of anaesthesia (Kain *et al*, 1998). However, the use of the extensive program might still be of clinical significance in the reduction of anxiety for these patients.

Campbell *et al* (2005) evaluated a computer-package for children undergoing short general anaesthetics for dental extractions. At the anaesthetic induction, the computer preparation package was significantly better at reducing anxiety and distress than verbal preparation alone. It was also significantly better at reducing anxiety and distress compared to a cartoon strip at recovery.

Therefore, research very clearly shows that preparation for surgery and anaesthesia is important. In view of the fact that many children consider the dental visit a stress-inducing situation, it is surprising that there has not been more research to evaluate preparation programs for paediatric dental patients. Furthermore, there have been no studies to evaluate the value of linking CBT to inhalation sedation, which might expand the use of IS to more dentally anxious children and adolescents.

1.5 THE USE OF LEAFLETS IN HEALTHCARE

Patients are often not very good at remembering what they have been told by the healthcare professional during a visit to the hospital or other healthcare setting. In fact, it has been estimated that most people remember less than 25% of what has been discussed during a consultation and often misunderstand what they have been told (Boundouki *et al*, 2004). However, additional written or visual information in the form of leaflets, which can be referred to later and discussed with family members, can help to increase knowledge retention (Boundouki *et al*, 2004).

1.5.1 *Patient information and education*

Patient information and education can be greatly enhanced by the distribution of leaflets that inform the reader about their medical condition or medication. The use and efficacy of leaflets have been researched in a variety of settings.

A randomised controlled trial was carried out in primary care to evaluate the effect of leaflets to empower patients in consultations (Little *et al*, 2004). Subjects were

randomly allocated to four groups. Patients in the first group were given a general leaflet, asking them to list issues they wanted to raise and explaining that the doctor wanted them to be able to talk and raise any issues that were concerning them. The patients in the second group received a depression leaflet, which listed the symptoms of depression and asked patients whether they had any of these symptoms and told them that the doctor wanted to discuss this. Patients in the third group received both leaflets and patients in the control group received none. It was found that the general leaflet increased patient satisfaction and was more effective with shorter consultations compared to controls while the depression leaflet had no significant effect (Little *et al*, 2004).

A computer package and a pamphlet, each containing the same information, were evaluated for nocturnal enuresis education in a cluster randomised controlled trial (Redsell *et al*, 2003). Children, aged between 5 and 16 years (mean 7.98), were randomised into three groups to receive either a computer package or a pamphlet whilst the control received no information at all. There were no statistically significant differences between the groups but the leaflet group had the highest proportion of children who were dry six months after treatment ended (Redsell *et al*, 2003).

The effect of a patient information leaflet regarding oral cancer, on improving knowledge, reducing psychological distress and increasing intention to accept an oral examination over a 2-month period was assessed in a randomised controlled trial (Boundouki *et al*, 2004). The study was carried out in two dental practices and patients were randomly allocated to a leaflet or no-leaflet group depending on which session they attended the surgery. The leaflet was found to have a significant effect on all three outcome measures (Boundouki *et al*, 2004).

1.5.2 Readability of leaflets

Patient information leaflets have to reinforce or even supplement professional advice (Bernardini *et al*, 2001). Therefore, if the leaflet is to be successful, the design, colour and print size should be appealing and the content easy to read (Bernardini *et al*, 2001). Researchers in various fields have conducted studies with commonly used leaflets to assess if patients thought that these leaflets were easy to read and understand.

A retrospective study to assess the readability of orthodontic patient information leaflets concluded that, overall, the 26 leaflets assessed were difficult to read with a fairly difficult mean readability level. This means that only 40% of the UK population would be able to understand the leaflets (Harwood and Harrison, 2004).

A large survey, carried out in Italy, showed that most patients read the package information leaflets provided with medicines but over half of them said that that were not easy to understand (Bernardini *et al*, 2000). In the second part of the same survey, the researchers investigated the consumer's attitude towards written information (Bernardini *et al*, 2001). It was found that most people, especially the ones with a lower level of education, did not like the use of colour in the package leaflets. It was also noted that the print size most commonly used in package leaflets, i.e. 9 points Didot, was too small and that most people prefer 10 and 11 points (Bernardini *et al*, 2001).

Two studies have been carried out to assess children's understanding of information leaflets. The first study tested children's understanding of pictograms and whether

pictograms improve understanding of leaflet information (Hameen-Anttila *et al*, 2004). Most children understood the meanings of the selected pictograms however; even well understood pictograms did not help children understand the leaflet information. The authors concluded that testing plain pictograms without incorporating them in their real context in the patient information leaflet may exaggerate their usefulness in leaflet information (Hameen-Anttila *et al*, 2004).

Barnett *et al*, (2005) assessed the impact that different styles of patient information leaflets, for randomised controlled trials, had on children's understanding. Children aged 9-11 years were randomly allocated into three groups each with a different style of the same information leaflet; question and answer format, story format or text format. The story format was found to be clearly superior in maximising children's understanding (Barnett *et al*, 2005).

1.5.2.1 Readability indices

As previously mentioned, leaflets designed for patient information have been found to be too difficult for patients to understand. One way to overcome this problem is to carry out a readability test to check the reading age of the pamphlet being produced. Readability tests are not accurate but they are a useful first step to finding out whether a leaflet is suitable for a cohort of patients. There are several ways of calculating readability using simple mathematical formulae (Secker and Polard, 1995).

Therefore, it is evident that leaflets help to supplement patient's understanding and recollection of what has been discussed in a consultation or advice given to them by a healthcare professional. However, leaflets are often pitched at the wrong level and therefore are not easy to understand. This obviously defeats the purpose of

distributing leaflets. Although the use of leaflets as a means of patient education and information has been researched quite extensively, it has not been possible to find any literature which shows that leaflets can be used to deliver cognitive behavioural therapy and coping skills to patients in either the medical or the dental setting.

1.6 SUMMARY OF LITERATURE REVIEW

Childhood dental anxiety is a common phenomenon with a worldwide reported prevalence ranging from 3 to 43%. Anxiety affects the dental health and care of the individual. It has been reported that highly anxious children have more dental disease, behaviour management problems and show more avoidance of dental care.

In a Cochrane review of dental sedation for anxious children published in 2006, the authors concluded that dental sedation studies have poor reporting, often not recording important data such as method of allocation, randomisation details and demographic characteristics. Furthermore, the statistical analysis used varied widely from one study to the other. Therefore, it is not possible to reach a conclusion with regards to best drug or method of dental sedation for treating dentally anxious patients. Interestingly, it was also noted that participants often completed treatment irrespective to which sedation group they were assigned (Matharu and Ashley, 2006). The authors stipulate that this might be because patients were either not anxious at baseline or else because many studies used not only restraint but also a combination

of different drugs. Therefore, it was virtually impossible to detect the efficacy of a sedative agent at preventing behaviour management problems.

Nitrous oxide inhalation sedation has been shown to be very efficacious as a behaviour management technique and in the most recent literature the effectiveness has ranged from 83 to 97%. Nitrous oxide inhalation sedation has been shown to have the highest success rate when used for orthodontic dental extractions usually in the older child (10.7–11.9 years). A success rate as high as 90-96.7% has been reported for this scenario (Shaw *et al*, 1996; Shepherd and Hill, 2000). However, in the case of comprehensive dental treatment, the success rate reported has been lower ranging between 83.9 and 90% (Hallonsten *et al*, 1983; Bryan, 2002; Naudi *et al*, 2006). The patients treated for comprehensive dental treatment have included a younger cohort of patients with a mean age range from 7.9 to 9.8 years. So, it can be concluded that, even though, nitrous oxide inhalation sedation has a high success rate it is still not 100% successful especially when used for the provision of comprehensive dental treatment and in the younger child.

In keeping with the findings of the Cochrane Review, regarding poor reporting in sedation studies, unfortunately the majority of studies, especially the most recent ones, fail to report why some patients do not manage to cope with the inhalation sedation technique. It is not clear if patients fail to complete dental treatment with inhalation sedation because they refuse to wear the nose-piece or because they do not manage to relax enough during the provision of nitrous oxide to have their treatment completed. However, we do have some data regarding the refusal to wear the nose-piece as some of the older studies have shown that between 4 and 23.5% of patients have refused to wear the nose-piece thus making sedation impossible to achieve

(Cooper *et al*, 1978; Major *et al*, 1981; Warren *et al*, 1983). Despite, the fact that there is not much evidence regarding the reasons behind failure of inhalation sedation in some patients, it is still obvious that this technique is not successful in all patients and that it might be possible for the dental team to expand its use by helping patients cope better with it, particularly acceptance of the nose-piece

Unfortunately, most children view the dental experience as a painful one and children's reactions to painful procedures are thought to be mediated by their cognitive-developmental level, previous experience, perceived control over the experience, parental support and their coping style (Franck and Jones, 2003).

Therefore, dental practitioners need to be able to help children cope with the dental experience by teaching them coping skills that they can use to overcome the anxiety associated these situations. Despite this, it is evident that children treated in most healthcare settings are not being taught coping techniques (Franck and Jones, 2003).

There have been a few published studies in the dental literature with the aim of investigating the effectiveness of teaching coping skills. The results show that children who are taught coping skills behave better during dental treatment than the ones that are not (Siegel and Peterson, 1980; Del Gaudio and Nevid, 1991).

However, there have never been any studies to show if teaching coping skills can help children cope better with inhalation sedation. If this is possible, then more patients will be able to accept inhalation sedation and the success rate of this technique can be further improved especially in the younger child and patients undergoing comprehensive dental treatment.

Cognitive behaviour therapy has been shown to be effective in the management of chronic pain, depressive disorders and anxiety disorders in children and adolescents. The use of cognitive behaviour therapy has not been extensively reported in dentistry and the studies that are available mainly deal with the adult dental population (Berggren *et al*, 2000; Willumsen *et al*, 2001). Both these studies report that CBT can be beneficial in the management of anxious dental patients. In the paediatric dental population role modelling has been investigated in a pilot study and the initial results are encouraging (Weinstein *et al*, 2003). Therefore, it is evident from the available literature that there has not been enough research done to assess the possible benefits of using cognitive behaviour therapy to help anxious paediatric patients achieve coping skills to use during dental treatment. In view of this, it can be concluded that further studies are required to examine if CBT can be used to help paediatric patients cope better in the dental situation especially if combined with inhalation sedation.

Paper-based packages are frequently used in health-care to aid patients remember what has been discussed during a consultation or as information in relation to medicines or certain medical conditions. Studies have shown that leaflets can help improve patient understanding and reinforce professional advice. No literature was found which looked into the provision of cognitive behaviour therapy via leaflets neither in the dental nor in the medical setting.

Chapter 2

Aim

2.1 AIM

The aim of this project is to develop and evaluate a cognitive pamphlet to help facilitate inhalation sedation treatment for anxious paediatric dental patients.

2.2 OVERVIEW OF THE PROJECT

The project was carried out in three parts. These will be explained in sequence in the following sections. In the first study the population sample was ascertained. This was done in the form of a retrospective case note review of the patients undergoing inhalation sedation at Glasgow Dental Hospital and School (GDH&S). In the second study a cognitive pamphlet was designed and evaluated qualitatively and modified. The third study was a single blind randomised controlled clinical evaluation of this modified pamphlet.

Chapter 3

**Determination of the characteristics of the sample of anxious
children referred for inhalation sedation:**

A retrospective case-note review

3.1 RETROSPECTIVE CASE-NOTE REVIEW

3.1.1 *Aim*

The purpose of the first study was to ascertain the profile of the children attending for treatment with inhalation sedation at the Paediatric Dentistry Department at Glasgow Dental Hospital and School (GDH&S), the largest inhalation sedation service in the West of Scotland. This was done so that we would be able to plan and design the pamphlet in such a way that it is suitable for the patients attending for treatment.

3.1.2 *Method*

All the patients who attended for dental treatment with nitrous oxide inhalation sedation at the Paediatric Dentistry Department, Glasgow Dental Hospital and School between 1st January 2005 and 31st December 2005 were identified from a computerised appointment booking system. The case-notes of all these patients were pulled from medical records and reviewed.

3.1.2.1 Data collection

The following data was collected using a specifically designed data collection sheet (Appendix 1):

- age
- gender
- partial postcode

This partial postcode was used to calculate the level of social deprivation based on the Carstairs Index (McLoone, 2004). This index provides DEPCAT (social deprivation category) scores ranging from 1 to 7 with 1 being the most affluent area and 7 the most deprived area and is a common method for reporting the level of social deprivation in Scotland (McLoone, 2004).

3.1.3 Results

A total of 153 patients attended for dental treatment with nitrous oxide inhalation sedation between 1st January 2005 and 31st December 2005. All the casenotes were available for analysis. The data collected was analysed using a basic Microsoft Excel worksheet.

The mean age of patients attending for inhalation sedation was 10.8 years (range: 5-16y, SD: 6.36) (Fig 3.1). There were more female patients (53.6%) than there were males (46.4%). As shown in figure 3.2 the number of children coming from postcodes with the highest level of social deprivation (DEPCAT 6-7) was 55 (35.9%).

Figure 3.1: Age ranges of the children undergoing IS at GDH&S

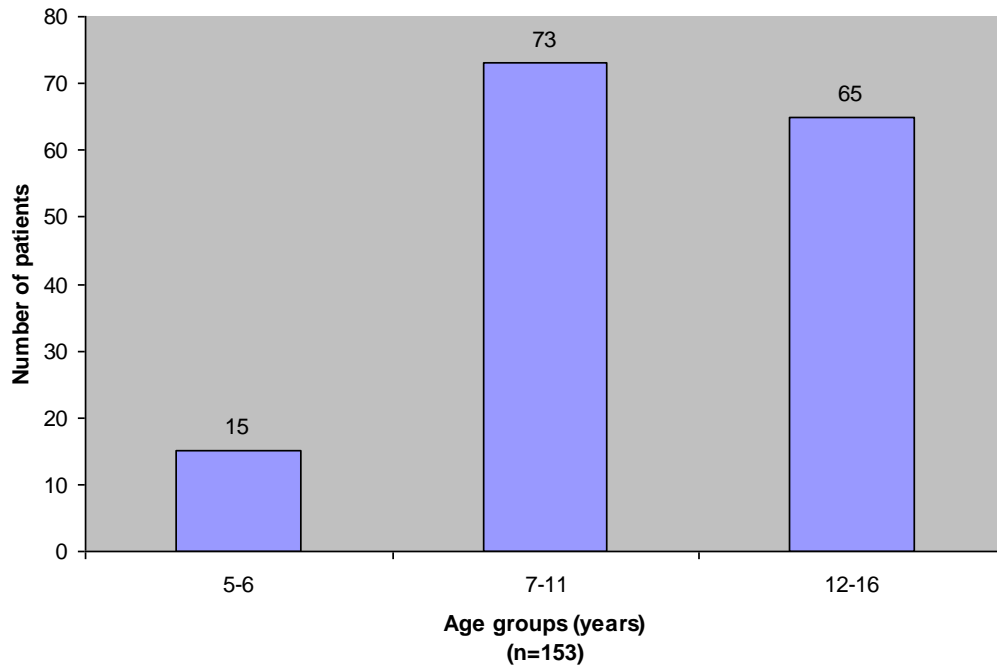
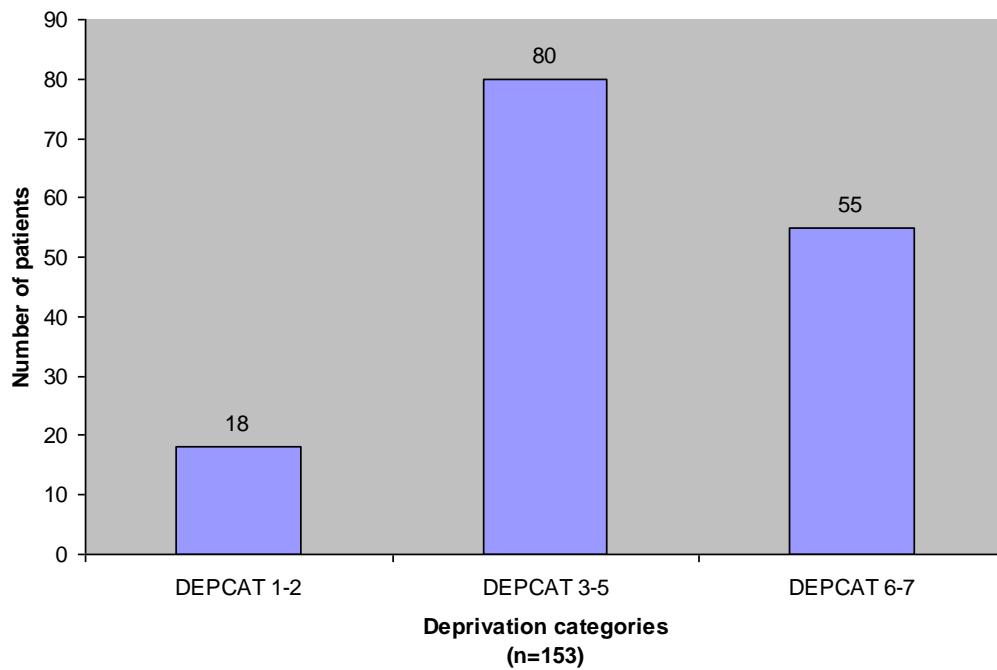


Figure 3.2: Deprivation categories of the children undergoing IS at GDH&S



3.1.4 Discussion

This sample of patients is older than that reported previously in the UK (Bryan 2002; Crawford, 1990; Blain and Hill, 1998). It is possible that since young children in the West of Scotland have extensive dental caries (Pitts, 1998), they are likely to have previously undergone GA extraction. The mean age of children referred for GA extractions in Scotland is 6.7 years (Macpherson *et al* 2005). The gender distribution is similar to that reported by previous studies (Bryan 2002; Crawford, 1990; Blain and Hill, 1998).

It has been recognised for many years that dental caries is related to social class, which in the case of children is a relationship to the household in which they live (Pitts, 1998). It was not possible to compare the level of deprivation in our sample to that of other studies as none of the inhalation sedation studies report the level of deprivation in their samples. However, the level of deprivation in the children in this sample reflects the levels of social deprivation in the Greater Glasgow NHS Health Board catchment area where DEPCAT 5, 6 and 7 make up 58% of the population and DEPCAT 7 alone contributes 30% (McLoone, 2004). Thus the proportion of socially deprived children treated with IS during this period is similar to the proportion of socially deprived children living locally.

3.1.5 Conclusion

The cognitive pamphlet should target children aged between 7 and 16 years and it should be equally appealing to male and female patients.

Chapter 4

The design and qualitative evaluation of a cognitive pamphlet

4.1 PAMPHLET DESIGN

4.1.1 *Aim*

The purpose of this study was to design a cognitive pamphlet to help children prepare better for their first IS visit. As such it should contain brief cognitive exercises that the patients can practise at home and be of the correct reading age.

4.1.2 *Method*

The pamphlet was designed to appeal to 7-16 year-old patients, the group identified by the first study as those most likely to undergo IS. It was designed in liaison with a psychologist (T. Musiello) to ensure that the content of the package was pitched at the right level for this cohort. It was produced using Microsoft Publisher 2003 and a 3-panel brochure format was chosen, as this was a convenient size and shape for the patient to use.

The pamphlet was made highly colourful and incorporated bright cartoon-style pictures. The font used was Trebuchet MS, which is a sans-serif font meaning that the letters do not have fine finishing strokes at the top and bottom. In sans-serif fonts, individual letters are easier to distinguish from one another and therefore they are usually easier for people to read (Secker and Pollard, 1995). The headings for each section were made to stand out by using bold fonts and highlighting with bordering or shading. Important points were also shaded and presented in a bulleted list format to attract the reader's attention to the content.

The first section of the pamphlet gave a brief description of anxiety and the symptoms associated with it, explaining that "it is normal to be anxious". The next sections contained three simple cognitive behaviour exercises namely;

1. controlled breathing
2. going to a relaxing place
3. positive thinking

In the final section, the patient was encouraged to praise him/herself for attempting to manage his/her anxiety. The first draft of the pamphlet is reproduced overleaf.

Helping you to cope better with inhalation sedation



Understanding Anxiety

When people become anxious or scared they often notice changes in their body. This is entirely normal when the body prepares itself to either run away or to face and fight the scary thing. There are number of signals that you can notice in your body when you are a bit anxious or worried.

- Lightheaded/feel
- Red face/feel
- Dry mouth/Lump in
- Butterflies in
- Sweat hands/Jelly
- Headache/Blurred
- Shaky
- Heart beats
- Difficulty



Controlled Breathing

This is a quick method to help you relax when you feel that you are becoming anxious. You can use this method anywhere and people often do not even notice what you are doing.

The idea is to think about your breathing and this will help you relax.

- Slowly draw in a deep breath
- Hold it for 5 seconds
- Then very slowly let it out.

As you breathe out say to yourself 'relax'.

Doing this a few times will help you regain control of your body and feel calmer.

RELAX



My Relaxing Place

With this method you chill out by thinking about a special place that you find restful. It could be a real place where you have been or a pretend place where you wish to go. Imagine a picture of it and make the picture as real as you can and think about it.



Break it down

Sometimes it is easier to get through a scary thing if you break it down to smaller steps.

- Tell yourself that you can cope for 10 minutes.
- When those 10 minutes are over tell yourself that you can cope for the next 10 minutes.
- Keep doing this until the session is over.

Praise yourself

When you try to beat your anxiety and face your fears, remember to praise yourself.

After all you deserve for having a try and even more if you manage to beat it.



4.2 QUALITATIVE EVALUATION

4.2.1 *Aim*

The aim of the qualitative evaluation was to ensure that the prototype pamphlet designed was suitable to use with 7-16 year-old paediatric patients.

4.2.2 *Method*

The pamphlet was evaluated by six paediatric dentists including three consultants and three specialist registrars. The evaluation took place in the office of the main researcher and was designed as a one-to-one structured interview. There was a specific set of questions related to the design and content of the leaflet. These questions are shown in Table 4.1.

Table 4.1: Structured interview questionnaire

1. What do you think of the cover?
2. If you only saw the cover what would you say the leaflet was about?
3. What do you think of the size of the leaflet?
4. Are the colours too bright, too dull or just right?
5. Is the print too small, too big or about right?
6. Is all the information in the leaflet necessary?
7. Is there any information missing from the leaflet?
8. Would most patients understand the leaflet?
9. What do you think of the length of the leaflet?
10. Do you think there is anything offensive in the leaflet?
11. What do you think of the leaflet overall?
12. Do you think this leaflet will help patients cope better with inhalation sedation?
13. Do you think it will help patients to accept the nose-piece better?
14. Any other comments?

4.2.2.1 *Readability*

The Gunning-Fog Index was used to assess the readability of the pamphlet.

It is known that the average reading age of adults in the UK is 9 to 10 years (Secker and Pollard, 1995). For the purpose of this thesis, subjects from 7 to 16 years will be targeted. Since we were not going to use a different leaflet for each age group but only one leaflet for all the patients in the target group, we set the readability of the pamphlet in the range of the 7 years or younger to ensure that it was possible for all the patients to understand the pamphlet.

4.2.2.1.1 The Gunning-Fog Index

The following is the algorithm used to determine the Gunning-Fog index:

1. Calculate the average number of words used per sentence (total number of words divided by the total number of sentences).
2. Calculate the percentage of difficult words in the sample (words with three or more syllables).
3. Add the totals together, and multiply the sum by 0.4.

4.2.3 RESULTS

4.2.3.1 *Qualitative study*

When all the interviews were completed, the responses received from each interviewee were tabulated. The answers received are given in tables 4.2-4.15:

Table 4.2: Answers to Question 1

What do you think of the cover?
<ul style="list-style-type: none"> • Good
<ul style="list-style-type: none"> • The younger child might not relate to the picture. The picture should be a bit more friendly for younger age groups, maybe have 2 leaflets
<ul style="list-style-type: none"> • Fine, writing clear and well highlighted, if children have not seen the IS machine before they might wonder what it is
<ul style="list-style-type: none"> • Nice layout and colours, maybe the cartoon should be in colour and bigger to make it more obvious
<ul style="list-style-type: none"> • I like it but the IS picture should be in colour
<ul style="list-style-type: none"> • Nice, colourful, not confusing

Table 4.3: Answers to Question 2

If you only saw the cover what would you say the leaflet was about?
<ul style="list-style-type: none"> • Information about having sedation
<ul style="list-style-type: none"> • IS
<ul style="list-style-type: none"> • Strategies to help you cope with IS
<ul style="list-style-type: none"> • Good description of what it is about
<ul style="list-style-type: none"> • What it says
<ul style="list-style-type: none"> • IS, as long as after explaining procedure

Table 4.4: Answers to Question 3

What do you think of the size of the leaflet?
<ul style="list-style-type: none"> • Good, not too big, reading in 4 separate pages, manageable to read
<ul style="list-style-type: none"> • Fine
<ul style="list-style-type: none"> • Good
<ul style="list-style-type: none"> • Fine
<ul style="list-style-type: none"> • Good, handy
<ul style="list-style-type: none"> • Good

Table 4.5: Answers to Question 4

Are the colours too bright, too dull or just right?
<ul style="list-style-type: none"> • Bright but nice
<ul style="list-style-type: none"> • Relaxing
<ul style="list-style-type: none"> • Just right
<ul style="list-style-type: none"> • Just right
<ul style="list-style-type: none"> • Just right
<ul style="list-style-type: none"> • Just Right

Table 4.6: Answers to Question 5

Is the print too small, too big or about right?
<ul style="list-style-type: none"> About right
<ul style="list-style-type: none"> Fine, bold print to highlight titles good, maybe language not appropriate for younger children
<ul style="list-style-type: none"> Ideal
<ul style="list-style-type: none"> Fine
<ul style="list-style-type: none"> Fine
<ul style="list-style-type: none"> OK

Table 4.7: Answers to Question 6

Is all the information in the leaflet necessary?
<ul style="list-style-type: none"> Maybe too many examples of symptoms of anxiety
<ul style="list-style-type: none"> Yes
<ul style="list-style-type: none"> Yes
<ul style="list-style-type: none"> Yes
<ul style="list-style-type: none"> Yes but there is something wrong with the spacing
<ul style="list-style-type: none"> Yes good introduction to let them know anxiety is normal

Table 4.8: Answers to Question 7

Is there any information missing from the leaflet?
<ul style="list-style-type: none"> • Should show a stronger link between the techniques described and IS
<ul style="list-style-type: none"> • No
<ul style="list-style-type: none"> • No
<ul style="list-style-type: none"> • Maybe should include an example of a relaxing place
<ul style="list-style-type: none"> • No
<ul style="list-style-type: none"> • No

Table 4.9: Answers to Question 8

Would most patients understand the leaflet?
<ul style="list-style-type: none"> • Yes
<ul style="list-style-type: none"> • No the younger ones would not
<ul style="list-style-type: none"> • Yes
<ul style="list-style-type: none"> • The younger ones might find it difficult, words like anxiety might be hard to understand
<ul style="list-style-type: none"> • Yes
<ul style="list-style-type: none"> • Younger children might not

Table 4.10: Answers to Question 9

What do you think of the length of the leaflet?
<ul style="list-style-type: none"> About right
<ul style="list-style-type: none"> Fine
<ul style="list-style-type: none"> Good
<ul style="list-style-type: none"> Fine
<ul style="list-style-type: none"> Fine
<ul style="list-style-type: none"> Good

Table 4.11: Answers to Question 10

Do you think there is anything offensive in the leaflet?
<ul style="list-style-type: none"> No
<ul style="list-style-type: none"> No
<ul style="list-style-type: none"> No
<ul style="list-style-type: none"> No
<ul style="list-style-type: none"> No
<ul style="list-style-type: none"> No

Table 4.12: Answers to Question 11

What do you think of the leaflet overall?
<ul style="list-style-type: none"> It is good, reassuring to the patients that there are others like them, that somebody else has thought how they can manage their anxiety. Helps to put the onus on the patient to manage their anxiety
<ul style="list-style-type: none"> Good idea, a bit too much for the younger ones, should be more pictorial
<ul style="list-style-type: none"> Very helpful
<ul style="list-style-type: none"> Quite good. Blocks of colour should maybe not overlap and not all bullet points are highlighted
<ul style="list-style-type: none"> It is good but it would be nice if the IS picture is in colour or if a real patient photo is used instead
<ul style="list-style-type: none"> Really good

Table 4.13: Answers to Question 12

Do you think this leaflet will help patients cope better with inhalation sedation?
<ul style="list-style-type: none"> Do not know
<ul style="list-style-type: none"> Not sure but worth trying it out to make patients more aware and to help them
<ul style="list-style-type: none"> If it is read properly, it should
<ul style="list-style-type: none"> It will begin to give them a message of what they can do
<ul style="list-style-type: none"> Yes, the breathing exercise is good. Good if given as pre-info and therefore the patient has a chance to think about it
<ul style="list-style-type: none"> Yes

Table 4.14: Answers to Question 13

Do you think it will help patients to accept the nasal-piece better?
<ul style="list-style-type: none"> • No
<ul style="list-style-type: none"> • No
<ul style="list-style-type: none"> • Do not know because there is no mention of the nasal-piece in the leaflet
<ul style="list-style-type: none"> • Only if it decreases the overall state of anxiety
<ul style="list-style-type: none"> • Only on the basis of decreasing the overall anxiety because you are not talking about it specifically in the leaflet
<ul style="list-style-type: none"> • Not sure but it might help them use it better

Table 4.15: Answers to Question 14

Any other comments?
<ul style="list-style-type: none"> • Title might not be entirely appropriate - maybe “ways of helping you cope better with IS”
<ul style="list-style-type: none"> • Maybe should include a worried face above the IS picture and a smiley face below it
<ul style="list-style-type: none"> • I like it
<ul style="list-style-type: none"> • The spacing is not good! Maybe should use more teenage cartoons
<ul style="list-style-type: none"> • Not sure children will understand words like anxious, praising
<ul style="list-style-type: none"> • No

4.2.3.2 Readability results

The readability age of the cognitive package was found to be approximately 7 years.

Calculation: Total number of words: 373

Total number of sentences: 32

Number of difficult words: 7

$$((373/32) + 7) \times 0.4$$

$$18.65625 \times 0.4 = \mathbf{7.4}$$

4.2.4 DISCUSSION

It was initially thought that the pamphlet would be evaluated by a focus group of clinicians and another focus group made up of patients who met the inclusion criteria of the study but were not taking part in the main study. However, due to clinical time constraints this proved not to be possible and therefore, the pamphlet was only evaluated by a focus group of clinicians. The evaluation of the pamphlet was conducted using a structured individual interview. This interview format was chosen because of some of its advantages; namely, that interviewees are more likely to answer all the questions if they are being asked directly rather than if they are completing a written questionnaire. Secondly, it is easy to clear up any misunderstanding in the question being asked or the answers given. However, structured interviews have their disadvantages since they are more time-consuming and the interviewee cannot reply anonymously.

The title of the pamphlet was originally 'Helping you to cope better with inhalation sedation'. It was suggested by two of the interviewees that this title did not effectively reflect the content of the pamphlet. Therefore, the title was changed to 'Ways of helping you cope better with inhalation sedation'. This meant that the title

suggested that the content of the pamphlet is actually giving patients potential ways of coping with their dental anxiety and, as such, is easier to understand.

Interviewees suggested that the original small black and white picture on the front cover of the pamphlet was not obvious enough and that if it was made more colourful and bigger it might convey the message that inhalation sedation is helpful more fully. It was also suggested that a photo of a patient actually having inhalation sedation could replace the picture. This possibility was considered however; because of the possible consent issues it was eventually abandoned. We did however, change the original black and white picture to a coloured one and increase the size. By doing this we kept to the cartoon theme of the rest of the pamphlet and also made the picture more obvious and the pamphlet more attractive.

The general layout of the pamphlet was mostly praised. However, one of the interviewees did think that the shaded blocks that bordered the title of each section were a bit overboard. This was because in the original pamphlet, some of the coloured blocks overlapped each other beneath the title. It was felt that this might be a bit confusing and detract from the importance of the title. Therefore, in line with this suggestion the titles were bordered with only one shaded block each, enough to make them stand out from the rest of the text.

In the original pamphlet only two out of the three bulleted lists were shaded. This gave the impression that the last exercise, which was not shaded, was maybe not as important as the others. In line with interviewee suggestions, all the bulleted lists were shaded in the same manner. It was also suggested that the 14 signs of anxiety listed in the original pamphlet, most of which were on the same line and separated by

a backlash, were providing an overload of information and might be confusing for the reader. Hence the signs were decreased to seven and none of the points contained more than one sign of anxiety.

There was a suggestion that the language in the pamphlet might not be easy to understand by all the age groups and that we should consider having two pamphlets for the younger and older age groups. However, the purpose of the final study is to evaluate one pamphlet that could be used universally for all the child patients. For this reason we relied on making the reading age of the leaflet suitable for all the patients involved. Therefore, we used the Gunning - Fog Index and this showed that the reading age is in the range of 7 years. Readability tests are relatively crude measures and they do not take into account the design and layout of the material. Furthermore, they also do not take into account different backgrounds, gender or age of the reader; factors which could all make a difference to the reader's interpretation of a pamphlet. However, they are a good first step to find out whether a pamphlet is suitable for the reader it is intended for (Secker and Pollard, 1995).

4.2.5 CONCLUSION

The changes made in the leaflet reflected the suggestions of the focus group interviewed. The title of the pamphlet was changed to better reflect the aim of the pamphlet. The picture on the front cover of the pamphlet was made bigger and more colourful to catch the reader's attention. The coloured blocks bordering the title of each section were decreased to avoid distracting the reader's attention. All the bullet points were highlighted to increase uniformity. The list of signs of anxiety was shortened so as not to confuse the reader. The amended and finalised pamphlet is reproduced overleaf

Ways of helping you cope better with inhalation sedation



Understanding Anxiety

When people become anxious or scared they often notice changes in their body. This is entirely normal and can often happen to people who are worried about having dental treatment. Some bodily changes caused by anxiety include:



- Feel faint
- Feel hot
- Dry mouth
- Butterflies in tummy
- Sweaty hands
- Jelly legs
- Difficulty breathing

This leaflet explains some exercises which may help you to control these feelings. Practice these simple tasks and use them to control your anxious feelings when having treatment with inhalation sedation.

Controlled breathing

This is a quick method to help you relax when you feel yourself becoming anxious. You can use this method anywhere and most people don't even notice you doing it. The idea is to think about your breathing and slow it down to help you relax.

- Slowly draw in a deep breath
- Hold it and count up to 5
- Then very slowly let it out.

As you breathe out say to yourself 'relax'. Doing this a few times will help you regain control of your body and feel calmer.



Practice this when you feel yourself starting to get worried or anxious.

My Relaxing Place

Use this to chill out by thinking about a special place that you find relaxing. It could be a real place where you have been or a pretend place where you wish to go.



Imagine a picture of it and make the picture as real as you can. Think about the colours, sounds and smells of the place.

Think positive

We often think about things in a negative way and this can make us feel anxious. Next time you are feeling scared try to change your negative thoughts to positive ones. You can do this by saying positive things to yourself:

- I can do this and I will manage

Repeat your positive message over and over to yourself.

Praise yourself

We are not always good at praising ourselves for doing something well.

When you try to beat your anxiety and face your fears, remember to praise yourself.

After all you deserve it for having a try and even more if you manage to beat your anxious feelings.

So remember to say well done

to yourself for trying to manage your fear.



Chapter 5

**A single blind prospective randomised controlled clinical
evaluation of a cognitive pamphlet designed to help children
better accept nitrous oxide inhalation sedation.**

5.1 RANDOMISED CONTROLLED TRIAL

5.1.1 *Aim*

The third and main part of the project is a single-blind randomised controlled clinical study. This aim of this study was to evaluate whether the cognitive package facilitated children's acceptance of inhalation sedation at their first dental visit.

5.1.2 *The Null Hypothesis*

The cognitive pamphlet does not help paediatric dental patients cope better with inhalation sedation.

5.1.3 *Research outcome measures*

The primary measure was whether the pamphlet helped children to accept the nose-piece. The secondary measures related to the overall compliance of the subject to accept the IS sedation and subsequently have treatment completed.

5.1.4 *Ethical Approval*

Ethical approval was obtained from the Glasgow West Local Research Ethics Committee. The committee initially requested some changes in relation to the time available for subjects and their parents to read the information sheets and the wording of the information sheets. Following these changes, the Ethics Committee approved both the study and the pamphlet which was given out to the patients recruited for the study. The 1) letter of approval, 2) letter for research and development, 3) the patient and parent information sheets and 4) the patient and parent consent forms are all reproduced in Appendix 2.

5.1.5 Method

5.1.5.1 Recruitment

Children and their parents were recruited for the study at the pre-sedation assessment clinic at the Paediatric Dentistry Department, Glasgow Dental Hospital and School and Primary Care Community Dental Service, Greater Glasgow and Clyde. Subjects were recruited by the main researcher or the researcher supervisor at the time of their sedation assessment visit.

Once it was established that the child was going to have dental treatment with inhalation sedation, the study was explained to the child and the accompanying adult. An explanatory sheet was given to the parents and the children explaining the aims of the study, anonymity and freedom to refuse to take part or to withdraw at a later date. Once the child had accepted to participate in the study written consent was obtained.

Following the sedation assessment visit, the subjects were randomly allocated to IS sessions. These were staffed by a variety of dental operators of different levels of experience. This is the normal practise in the unit.

5.1.5.1.2 Inclusion Criteria

Children were suitable for the study if:

- Referred for inhalation sedation
- Aged between 7 and 16 years
- Their first language was English
- They had no learning disability

5.1.5.2 Randomisation

The children were then randomised into the experimental or control group, stratified by age, gender and level of social deprivation, using a computer-generated randomisation grid.

5.1.5.2.1 Experimental Group

The children in the experimental group received the cognitive pamphlet as well as a standard inhalation sedation information sheet.

5.1.5.2.2 Control Group

The children in the control group received the standard information sheet only, which is reproduced in appendix 3.

5.1.5.3 Data collection

5.1.5.3.1 Prior to inhalation sedation

All the participants were asked to take tests to quantify their dental anxiety prior to dental treatment at the recruitment stage. The Modified Child Dental Anxiety Survey (MCDAS) questions were asked by the researcher and the child was asked to point to the face on the Facial Image Scale (FIS) that best represented their feelings. It was thought that this would be an easier assessment method for the younger child as they can relate better to the pictograms of the FIS rather than have to give verbal answers to the questions of the MCDAS.

5.1.5.3.1.2 The Modified Child Dental Anxiety Survey (MCDAS)

The MCDAS (Table 5.1) presents the subjects with 8 questions related to dental treatment for which there are five answers. The patient is asked to choose the answer that best describes the way that they feel. The scale has been validated to show that it may be useful in trials to assess the benefits of interventions to assist children receive dental treatment (Wong *et al*, 1998). Humphris *et al* (1995) concluded that a score of 31 out of 40 signifies dental phobia.

5.1.5.3.1.3 The Facial Image Scale (FIS)

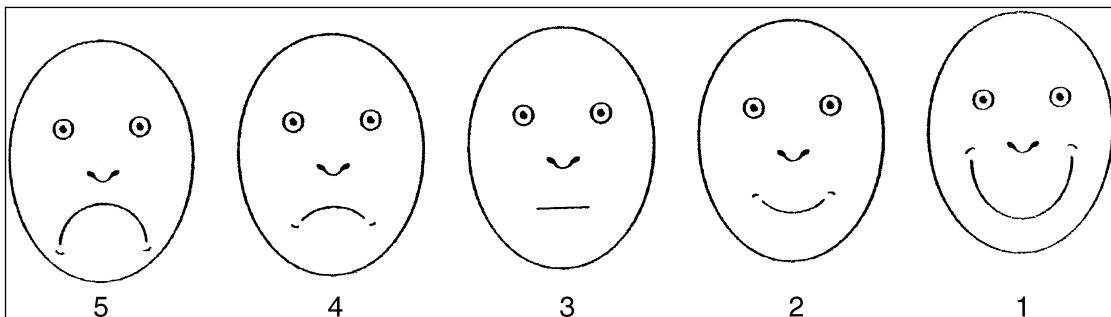
The Facial Image Scale (Fig. 5.1) comprises a row of five faces ranging from very happy to very unhappy. The scale is scored by giving a value of one to the most positive affect face and five to the most negative affect face. The FIS has been found to be a valid measure of dental anxiety for employment with young children in the clinical context (Buchanan and Niven, 2002).

Howard and Freeman (2007) conducted a study with a large sample of children aged 5 to 12 years to evaluate the psychometric properties of the faces version of the MCDAS. They found that this scale is a reliable measure of dental anxiety in children aged 8-12 years, demonstrating good reliability and validity. The normative value for dental anxiety was 19.81 and those children who scored 26 or over were shown to have a 51% probability of being extremely dentally anxious (Howard and Freeman, 2007).

Table 5.1: Modified Child Dental Anxiety Survey

<p>Questions:</p> <p>How do you feel about:</p> <ol style="list-style-type: none">1. Going to the dentist generally?2. Having your teeth looked at (check - up)?3. Having teeth scraped and polished?4. Having an injection in the gum to freeze a tooth?5. Having a tooth drilled?6. Having a tooth taken out?7. Being put to sleep to have treatment?8. Having a mixture of gas and air to help you relax but which will not put you to sleep? <p>Answers:</p> <p>1 = relaxed / not worried 2 = worried a little 3 = fairly worried 4 = worried a lot 5 = extremely worried</p>
--

Figure 5.1: The Facial Image Scale



5.1.5.3.2 During inhalation sedation

5.1.5.3.2.1 Equipment used for inhalation sedation

The inhalation sedation machine used in the department is a Quantiflex MDM unit. The nose-pieces used are Porter brown Paediatric Hoods which are manufactured by Porter Instruments in Philadelphia, USA and distributed by RA medical in the UK. They consist of an autoclavable grey hood with a detachable inner lining and they do not have any particular smell (Figure 5.2 and 5.3).

5.1.5.3.2.2 Blinded operators

The operators were asked to assess the overall compliance of the subjects on the first appointment for treatment under inhalation sedation using two different scales. These were the 5-point Global Rating Scale (GRS, Table 5.2) and the Visual Analog Scale (VAS, Fig 5.2). The operator was not aware of whether the children were in the control or experimental groups. The operators were 1 consultant, 2 specialists, 2 salaried dental officers and 6 senior house officers.

5.1.5.3.2.1.3 The 5-point Global Rating Scale

The Global Rating Scale, shown in table 5.2, is a measure of both the successful completion of treatment at the visit and of the dentist's perception of the child's anxiety and it has been found to be simple to use and to reliably evaluate the responses of anxious paediatric patients to treatment (Hosey and Blinkhorn, 1995).

5.1.5.3.2.1.4 The Visual Analog Scale

This scale consists of a 10cm horizontal line with two poles: unsatisfactory and satisfactory. It can be used to self-report or as an observational tool. In the present study the VAS was used as an observational tool. A vertical line across the horizontal

line was used to mark the operator's assessment of the child's behaviour. The point where the vertical line crossed the horizontal line was measured with a ruler to give a score to the nearest cm. The VAS has been validated for use with anxious dental patients (Parkin SF, 1989) and when compared to other scales it was found to be more sensitive and simpler to use (Hosey and Blinkhorn, 1995).

Figure 5.2 Nose-piece and inner lining



Figure 5.3 Nose-piece and inner lining assembled



Table 5.2: Global Rating Scale

5 = excellent 4 = very good 3 = good 2 = fair 1 = poor/aborted	<input style="width: 60px; height: 40px;" type="text"/>
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Unsatisfactory

Satisfactory

Figure 5.4: Visual Analog Scale

Table 5.3: Houpt Scale

Rating for sleep 1 Fully awake, alert 2 Drowsy, disorientated 3 Asleep	<input style="width: 60px; height: 40px;" type="text"/>
Rating for movement 1 Violent movement interrupting treatment 2 Continuous movement making treatment difficult 3 Controllable movement that does not interfere with treatment 4 No movement	<input style="width: 60px; height: 40px;" type="text"/>
Rating for crying 1 Hysterical crying that demands attention 2 Continuous, persistent crying that makes treatment difficult 3 Intermittent, mild crying that does not interfere with treatment 4 No crying	<input style="width: 60px; height: 40px;" type="text"/>
Rating for overall behaviour 1 Aborted no treatment rendered 2 Poor treatment interrupted, only partial treatment completed 3 Fair treatment interrupted, but eventually all completed 4 Good difficult, but all treatment performed 5 Very good some limited crying or movement 6 Excellent no crying or movement	<input style="width: 60px; height: 40px;" type="text"/>

5.1.5.3.2.2 Blinded observers

The children's first treatment session under IS was video-taped and the children's behaviour was further assessed by two blinded observers. The scales used were a dichotomous scale "Yes or No" on nose-piece acceptance, the 5-point Global Rating Scale (Table 5.2), a 10cm Visual Analog Scale (Fig 5.2) and the Houpt Scale (Table 5.3). These were each used at four time points:

1. introduction to the nose-piece
2. fitting the nose-piece
3. breathing in and out of the nose-piece (measured by observing the movement of the reservoir bag)
4. start of the operative procedure

5.1.5.3.2.2.1 Blind observer training and calibration

The lead researcher and the two blinded observers were involved in the training and calibration process.

5.1.5.3.2.2.1.1 Training

The observers were educated in the aims of the study and in what was required of them. They were then shown video clips of paediatric patients receiving sedation and they were trained in scoring the behaviour of the patient using the three scales to be used in the study namely the VAS, GRS and the Houpt scales. The observers were then shown further video clips and asked to discuss and agree on scoring the behaviour of the patients in the new videoclips.

5.1.5.3.2.2.1.2 Calibration

Each individual observer was then calibrated against the other. The first ten clips that the observers rated were used to calculate the Cohen's Kappa for inter-rater reliability.

5.1.5.3.2.2.2 The Houpt Scale

Developed by Nazif (1971), this scale measures behaviour by rating sleep, movement, crying and overall behaviour. Houpt recommended that scoring is done at specific time spots in the visit. In the present study, the scores from the four categories of the Houpt scale were summed up to give an overall time-point score at each of the four time-points observed.

The Houpt Scale was found to be a reliable tool if used to score a patient's response to specific items of treatment, such as local anaesthetic injection (Hosey and Blinkhorn, 1995). In this study, the observers were asked to score at the four different time points, namely introduction to the nose-piece, fitting the nose-piece, breathing in and out of the nose-piece and start of the operative procedure.

5.1.5.4 Statistical Analysis

5.1.5.4.1 The primary outcome measure

The primary outcome measure was the success/failure of the fitting of the nose-piece.

The success rates in the two groups, of the fitting of the nose-piece, were compared using the Chi -square test.

5.1.5.4.2 The secondary outcome measure

- Secondary outcome measures of the Global Rating Scale as scored by the blinded observers were compared between groups using the Chi-square Fisher Exact test on the tabulated data.
- The average Houpt scores and the Visual Analog Scale were compared between groups using medians and the Mann-Whitney test, since the data for this scale was not normally distributed.

5.1.5.4.3 Power calculation

The sample size in each group required to detect different proportions p_1 with different p_0 at the 5% significance level with power 80% assuming equal groups is shown in table 5.4. The proportion of patients who will accept the nose-piece in the control group is p_0 while the proportion of patients who will accept the nose-piece in the experimental group is represented by p_1 . This means that if only 50% of controls accept the nose-piece but 90% of the pamphlet group accept it then 24 subjects are required in each group. Therefore, in order to see an improvement of 40% between the two groups, it will be necessary to recruit a total of 48 subjects. The outcome measure is acceptance of the nose-piece while the intervention is a cognitive pamphlet. Fisher exact test was used for statistical analysis.

Table 5.4: Power calculation

	p0				
	<i>0.5</i>	<i>0.6</i>	<i>0.7</i>	<i>0.8</i>	<i>0.9</i>
p1					
<i>0.5</i>					
<i>0.6</i>	407				
<i>0.7</i>	103	376			
<i>0.8</i>	44	91	313		
<i>0.9</i>	24	38	72	219	

5.1.5.4.4 Inter- and intra-rater observer reliability

The inter and intra rater reliability between the two blinded observers was determined using Cohen's Kappa. Landis and Koch (1977) categorised Kappa values as follows:

- Kappa 0.14-0.60 represents moderate agreement
- Kappa 0.61-0.80 represents substantial agreement
- Kappa 0.81-0.99 represents almost perfect agreement
- Kappa 1 represents perfect agreement

The first ten study clips that the observers rated were shown to them again later without them knowing that they were rating the same clip twice. The results obtained for these clips were then rated against each other for each observer and then against the other observer to give intra and inter-rater reliability scores respectively.

5.1.6 *Results*

5.1.6.1 Sample

Patients were assessed for eligibility from August 2006 till October 2007 in the Glasgow Dental Hospital and School and the Community Dental Service in Glasgow. The total number of patients assessed was 130. The number of patients who met the inclusion criteria was 67 of which 16 refused to participate in the study and 5 could not be recruited for other reasons. Out of the 46 patients who were recruited to the study 11 were lost to follow-up. Therefore, the final number of patients participating in the study was 35, of which 11 (31.5%) were recruited from the Community Dental Services. Eighteen were male and the mean age was 10.2 years (7-14). Thirteen (34.2%) were in the highest level of social deprivation. The preoperative anxiety scores were very similar for both groups and the mean values (24.6 and 24.9). This is higher than the normative value for dental anxiety (19.8) for the scale used (Howard and Freeman, 2007) meaning that this sample of patients can be considered as dentally anxious. Further demographic details are shown in Table 5.5.

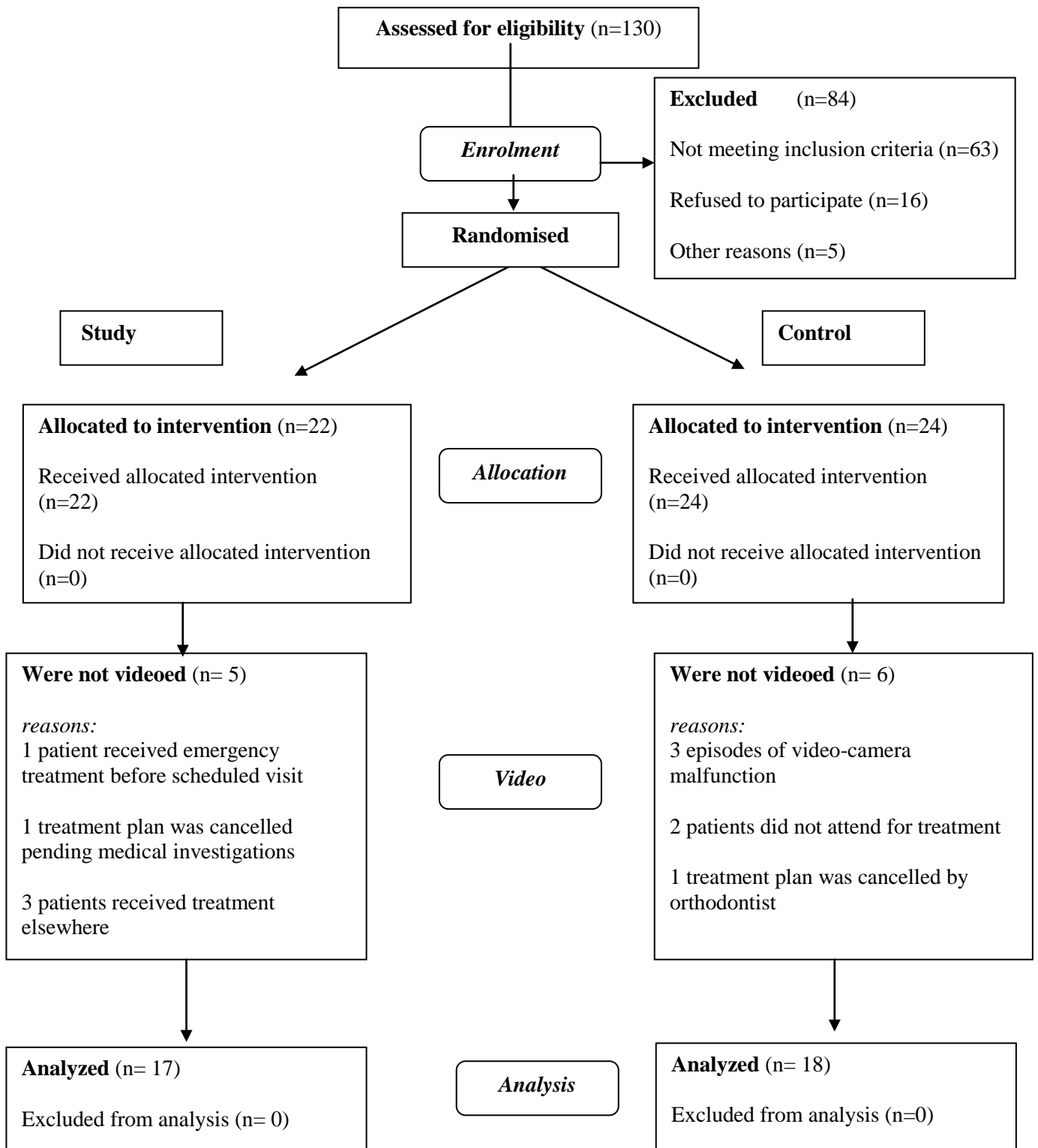
Table 5.5: Demographic details of patients in each group

	Study Group (n=17)	Control Group (n=18)
Gender (number of recruits)		
Male	8	10
Female	9	8
Age (number of recruits)		
7-11	11	14
12-16	6	4
DEPCAT (number of recruits)		
1-2	1	2
3-5	10	10
6-7	6	6
Anxiety (MCDAS & FIS)		
Mean	24.6	24.9
Range	15-31	18-32
SD	4.03	4.46

5.1.6.2 Randomisation

The consort flowchart, demonstrating the randomisation is shown in Table 5.6.

Table 5.6: The Consort Flowchart



5.1.6.3 Subjects' behaviour as scored by operators after treatment

The operator scores by group are shown in Table 5.7.

Table 5.7: Operator scores after treatment

	Study Group (n=17)	Control Group (n=18)
Global Rating Scale		
number (%) patients in each category		
5 = excellent	3 (17.6)	3 (16.7)
4 = very good	8 (47.1)	6 (33.3)
3 = good	2 (11.8)	2 (11.1)
2 = fair	3 (17.6)	5 (27.8)
1 = poor/aborted	1 (5.9)	2 (11.1)
Visual Analog Scale		
Mean	6.25	6.54
Range	1-10	1-10
SD	7.9	8.5

5.1.6.4 Primary Outcome Measure – acceptance of nose-piece

The primary outcome measure scored from the video-recording by the blinded observers was the acceptance of the nose-piece. There was 100% agreement between the observers. The results are shown in Table 5.8. The Chi-squared test showed that there was no statistical difference between the groups (p value= 0.324).

Table 5.8: Primary Outcome Measure: acceptance of the nose-piece

	Study Group (n=17)	Control Group (n=18)
Accepted	17	17
Did not accept	0	1

5.1.6.5 Secondary Outcome Measure: subjects' behaviour during treatment

The independent blinded observer scores for the four time points are shown in Tables 5.9 and 5.10 for observer 1 and observer 2 respectively. The level of significance for both the Mann-Whitney and the Chi-Square tests was set at 0.05. The results show that there is no statistically significant difference between the two groups.

Table 5.9a: Visual Analog Scale scores for observer 1

	Study Group (n=17) Median (IQR)*	Control Group (n=18) Median (IQR)*	P-value Mann- Whitney test
Time-point 1 (introduction to nose- piece)	7.5 (2.0) (missing data = 5)	8.0 (4.0) (missing data = 7)	0.740
Time point 2 (fitting of nose-piece)	8.0 (2.0) (missing data = 2)	9.0 (2.0) (missing data = 2)	0.984
Time point 3 (breathing in and out of nose-piece)	8.0 (1.0) (missing data = 0)	9.0 (1.0) (missing data = 1)	0.586
Time point 4 (start of operative procedure)	7.0 (5.0) (missing data = 0)	8.0 (5.0) (missing data = 1)	0.708

*Interquartile range

Table 5.9b: Houpt scores for observer 1

	Study Group (n=17) Median (IQR)*	Control Group (n=18) Median (IQR)*	P-value Mann- Whitney test
Time-point 1 (introduction to nose- piece)	14.0 (1.75) (missing data = 5)	15.0 (1.0) (missing data = 7)	0.316
Time point 2 (fitting of nose-piece)	14.0 (2.0) (missing data = 2)	15.0 (1.75) (missing data = 2)	0.216
Time point 3 (breathing in and out of nose-piece)	14.0 (2.0) (missing data = 0)	14.0 (2.0) (missing data = 1)	0.919
Time point 4 (start of operative procedure)	12.0 (4.0) (missing data = 0)	13.0 (3.0) (missing data = 1)	0.290

* Interquartile Range

Table 5.9c: Global Rating Scale scores for observer 1

	Study Group (n=17)	Control Group (n=18)	P-value Chi-square test
	Number of patients	Number of patients	
Time-point 1 (introduction to nose- piece)	(missing data = 5)	(missing data = 7)	
5	0	0	
4	9	8	
3	3	3	
2	0	0	
1	0	0	1
Time point 2 (fitting of nose-piece)	(missing data = 2)	(missing data = 2)	
5	0	2	
4	14	10	
3	1	2	
2	0	2	
1	0	0	0.219
Time point 3 (breathing in and out)	(missing data = 0)	(missing data = 1)	
5	0	1	
4	11	9	
3	6	7	
2	0	0	
1	0	0	0.728
Time point 4 (start of operative procedure)	(missing data = 0)	(missing data = 1)	
5	5	8	
4	6	5	
3	4	1	
2	2	1	
1	0	2	0.377

Table 5.10a: Visual Analog Scale scores for observer 2

	Study Group (n=17) Median (IQR)*	Control Group (n=18) Median (IQR)*	P-value Mann- Whitney test
Time-point 1 (introduction to nose- piece)	8.5 (2.0) (missing data = 5)	9.0 (6.0) (missing data = 7)	0.525
Time point 2 (fitting of nose-piece)	8.0 (2.0) (missing data = 2)	9.0 (1.75) (missing data = 2)	0.470
Time point 3 (breathing in and out of nose-piece)	8.0 (1.5) (missing data = 0)	8.0 (1.5) (missing data = 1)	0.973
Time point 4 (start of operative procedure)	7.0 (4.0) (missing data = 0)	8.0 (4.5) (missing data = 1)	0.683

*Inter-quartile range

Table 5.10b: Houpt scores for observer 2

	Study Group (n=17) Median (IQR)*	Control Group (n=1) Median (IQR)*	P-value Mann- Whitney test
Time-point 1 (introduction to nose- piece)	15.0 (2.0) (missing data = 5)	15.0 (2.0) (missing data = 7)	0.740
Time point 2 (fitting of nose-piece)	15.0 (2.0) (missing data = 2)	15.0 (1.5) (missing data = 2)	0.953
Time point 3 (breathing in and out of nose-piece)	15.0 (2.0) (missing data = 0)	15.0 (2.0) (missing data = 1)	0.865
Time point 4 (start of operative procedure)	13.0 (2.0) (missing data = 0)	15.0 (3.5) (missing data = 1)	0.413

*Inter-quartile range

Table 5.10c: Global Rating Scale scores for observer 2

	Study Group (n=17)	Control Group (n=18)	p-value Chi- square test
	Number of patients	Number of patients	
Time-point 1 (introduction to nose- piece)	(missing data = 5)	(missing data = 7)	
5	2	2	
4	8	6	
3	1	1	
2	1	2	
1	0	0	0.909
Time point 2 (fitting of nose-piece)	(missing data = 2)	(missing data = 2)	
5	2	6	
4	12	7	
3	1	1	
2	0	2	
1	0	0	0.125
Time point 3 (breathing in and out)	(missing data = 0)	(missing data = 1)	
5	5	3	
4	8	10	
3	4	4	
2	0	0	
1	0	0	0.898
Time point 4 (start of operative procedure)	(missing data = 0)	(missing data = 1)	
5	5	7	
4	6	5	
3	3	2	
2	3	1	
1	0	2	0.574

5.1.6.6 Inter-observer reliability

The Cohen's Kappa scores achieved for each time-point are shown in table 5.11 and the percentage agreement is shown in table 5.12.

Table 5.11: Inter-observer reliability – Cohen’s Kappa

Kappa		Observer 1												
		Visual Analog Scale				Global Rating Scale				Haupt Scale (overall)				
		1	2	3	4	1	2	3	4	1	2	3	4	
Observer 2	Visual Analog Scale	1	0.3											
		2		0.1										
		3			0.5									
		4				0.6								
	Global Rating Scale	1					NC							
		2						0.1						
		3							0.1					
		4								0.4				
	Haupt Scale	1									NC			
		2										0.2		
		3											0.1	
		4												0.1

NC: almost identical assessments cannot compute Kappa

Kappa 0.14-0.60 represents moderate agreement

Table 5.12: Inter-observer reliability – percentage agreement

%		Observer 1												
		Visual Analog Scale				Global Rating Scale				Haupt Scale (overall)				
			1	2	3	4	1	2	3	4	1	2	3	4
Observer 2	Visual Analog Scale	1	60											
		2		60										
		3			70									
		4				70								
	Global Rating Scale	1					90							
		2						60						
		3							50					
		4								60				
	Haupt Scale	1									90			
		2										70		
		3											50	
		4												30

5.1.5.7 Intra-observer reliability

The observers watched and re-scored the first ten clips they had previously rated and the Cohen's Kappa and percentage scores at each time-point are shown in the following tables.

Table 5.13: Intra-observer reliability for observer 1 – Cohen’s Kappa

Kappa		Observer 1												
		Visual Analog Scale				Global Rating Scale				Houpt Scale (overall)				
		1	2	3	4	1	2	3	4	1	2	3	4	
Observer 1	Visual Analog Scale	1	0.3											
		2		0.4										
		3			0.1									
		4				0.7								
	Global Rating Scale	1					1.0							
		2						0.2						
		3							0.4					
		4								0.4				
	Houpt Scale	1									NC			
		2										0.2		
		3											0.3	
		4												0.3

NC: identical assessments cannot compute Kappa

Kappa 0.14-0.60 represents moderate agreement

Kappa 0.61-0.80 represents substantial agreement

Table 5.14: Intra-observer reliability for observer 1 - percentage

%		Observer 1											
		Visual Analog Scale				Global Rating Scale				Haupt Scale (overall)			
		1	2	3	4	1	2	3	4	1	2	3	4
Observer 1	Visual Analog Scale	1	60										
		2		70									
		3			50								
		4				80							
	Global Rating Scale	1					100						
		2						50					
		3							70				
		4								60			
	Haupt Scale	1									100		
		2										70	
		3											60
		4											

Table 5.15: Intra-observer reliability for observer 2 – Cohen’s Kappa

Kappa		Observer 2												
		Visual Analog Scale				Global Rating Scale				Haupt Scale (overall)				
		1	2	3	4	1	2	3	4	1	2	3	4	
Observer 2	Visual Analog Scale	1	0.2											
		2		0.2										
		3			0.6									
		4				0.6								
	Global Rating Scale	1					NC							
		2						0.3						
		3							0.1					
		4								0.7				
	Haupt Scale	1									NC			
		2										1.0		
		3											0.2	
		4												0.7

NC: identical assessments cannot compute Kappa

Kappa 0.14-0.60 represents moderate agreement

Kappa 0.61-0.80 represents substantial agreement

Kappa 1.0 represents perfect agreement

Table 5.16: Intra-observer reliability for observer 2 – percentage agreement

%		Observer 2												
		Visual Analog Scale				Global Rating Scale				Houpt Scale (overall)				
			1	2	3	4	1	2	3	4	1	2	3	4
Observer 2	Visual Analog Scale	1	70											
		2		60										
		3			80									
		4				70								
	Global Rating Scale	1					90							
		2						60						
		3							60					
		4								80				
	Houpt Scale	1									80			
		2										100		
		3											60	
		4												80

Chapter 6

Discussion

6.1 WAS THE PAMPHLET SUCCESSFUL?

The present study shows that the pamphlet was not successful to either help patients accept the nose-piece or improve their behaviour during treatment.

6.2 STUDY SAMPLE

6.2.1 *Size*

When the study was being planned it was thought that all the subjects could be recruited from the Paediatric Dentistry Department, Glasgow Dental Hospital and School. This was because the retrospective case-note review conducted previously to determine the characteristics of children referred for treatment with inhalation sedation showed that a total of 153 patients were treated in the department during 2005 (Chapter 3). However, after recruitment had been ongoing for approximately nine months, it became obvious that this was not possible so recruitment was extended to the Community Dental Service in the Greater Glasgow and Clyde area.

Although, a total of 130 potential IS patients were assessed for eligibility to be included in the study, the final number of who completed the study was disappointing. The main reason for exclusion at the recruitment stage was failure to meet the inclusion criteria (57 patients were referred for treatment with intravenous sedation or general anaesthesia, 4 patients were too young to participate in the study and another 2 patients did not speak English as their first language). Some of the patients who did meet the inclusion criteria refused to participate because they did not wish to be videotaped during treatment. Others refused because of time constraints.

The relatively small size of the sample might be a possible reason for failure to find a difference between the two groups. Considering that the literature indicated that the maximum rate of refusal to wear the nose-piece might be about 20% then, according

to the power calculation, in order to see an improvement in the acceptance of the nose-piece from 70% in the control group to 90% in the study group, we required a sample of 72 subjects per group. The final number of patients in this study was 35. Therefore, there were not enough patients in the study to be able to see an improvement in acceptance of the nose-piece.

Although the sample size in the present study did not achieve statistical power, it is similar to other sedation studies involving nitrous oxide inhalation sedation. The studies included in the Cochrane review (Matharu and Ashley, 2006) which evaluate the efficacy of nitrous oxide in comparison to a placebo have a sample size ranging from 24 to 35 (Lindsay and Roberts, 1980; Nathan *et al*, 1988 & Primosch *et al*, 1999) and 56 for the study by Veerkamp *et al* (1993). On the other hand two studies which looked at the success of inhalation sedation compared to general anaesthesia had a much larger sample sizes than the present study (Blain and Hill, 1998 & Shephard and Hill, 2000). Therefore, the sample in the present study can be considered to be comparable to the usual sample size for inhalation sedation studies.

6.2.2 Age, gender and social deprivation

The two groups in the present study were well-matched in terms of gender, age and social deprivation. When compared to the retrospective case-note review (Chapter 3) it can be seen that the gender of the sample and the distribution of patients in the deprivation categories are very similar. However, the age distribution of the samples differ markedly with 71.4% of subjects falling in the 7-11 year age group in the present study and only 47.7% belonging to the same age group in the retrospective case-note review. Therefore, the sample of patients in this study is younger than would have been anticipated from the results of the retrospective case-note review.

This may imply that the age distribution in this study is not representative of the population of patients attending the Glasgow Dental Hospital. A possible explanation for this could be the fact that the subject sample in the present study is a mixture of patients from both the Dental Hospital and the Community Dental Service. It is possible that the younger patients attending the sedation assessment clinics at the Glasgow Dental Hospital are patients who might have already had previous failed attempts at treatment with inhalation sedation in the Community Dental Service and therefore they are more likely to be referred for treatment under general anaesthesia when seen at the Dental Hospital.

The age of the sample could also have had an effect on the impact of the pamphlet. Branson *et al* (1988) showed that children aged between 4 and 7 years usually use behaviour oriented coping strategies, while older children (8-10 years) start to supplement but not replace behaviour coping strategies with an increasing repertoire of cognitive coping strategies. It has also been shown that although all children benefit from CBT, younger children (5-13 years) benefit less (Durlak *et al*, 1991). Therefore, although the pamphlet was designed under the guidance of a psychologist, it may still have not been pitched at the right level for this age group.

6.3.3 *Preoperative anxiety levels*

The preoperative anxiety scores were very similar for both groups and the mean values (24.6 and 24.9) were higher than the normative value for dental anxiety (19.8) for the scale used (Howard and Freeman, 2007) meaning that this sample of patients can be considered as dentally anxious. Moreover, 15 subjects scored over 26 on the MCDAS/FIS scale and this is the cut-off point for extreme dental anxiety (Howard and Freeman, 2007). The level of preoperative anxiety found in this sample was

comparable to that reported by Alexopoulos *et al* (2007) who reported a mean preoperative anxiety level of 24.8 using the MCDAS in a group of patients attending for treatment with inhalation sedation at the same dental unit.

In another study it was shown that the mean preoperative anxiety level as measured by the MCDAS in a group of children who chose to have dental treatment with inhalation sedation as opposed to general anaesthesia was 19.4 (Arch *et al* 2001). This is similar to the normative value for the scale but lower than the level reported in the present study.

The high level of anxiety found in the present sample could also have affected the success rate of the pamphlet. In their Cochrane systematic review, James *et al* (2005) showed that CBT induced a remission in only 56% of paediatric patients suffering from mild to moderate anxiety disorders. In a meta-regression of factors that may predict outcome of CBT for depression, panic disorder and generalised anxiety disorder, Haby *et al* (2005) concluded that CBT may be less effective when used in people with severe disorders.

6.3 FACTORS RELATING TO OPERATORS

A limitation of the study is that treatment with inhalation sedation was performed by eleven different operators who had different levels of experience. Inhalation sedation is a very suggestive treatment modality and the operator's manner is important. Therefore, this could have impacted on the way that the subjects behaved during treatment. Ideally, in a study involving inhalation sedation, treatment of all the patients should be carried out by a single operator but this was not possible in the present study due to waiting lists for treatment with inhalation sedation. Another

reason for multiple operators was that some of the patients were recruited from the community dental service and therefore, their treatment had to be carried out in their respective community dental clinic and different clinicians work in the different clinics. The level of experience of the operator did not affect either group more than the other.

6.4 OBSERVER RELIABILITY

It has to be acknowledged that despite training and calibration on more than one occasion the agreement between the observers remained poor. The Cochrane Database Review of dental sedation (Matharau and Ashley, 2006) lists the scales used to assess behaviour in the studies included in the review. There was only one study (McKee, 1990) which used all the scales used in the present study, namely Houpt Scale, Visual Analog Scale, a dichotomous scale and Global Rating Scale. The researchers used a single trained observer who scored the first three scales while the operator scored the GRS. No intra-rater reliability scores were recorded for this study. Twenty-one of the studies included in the Cochrane review used the Houpt scale. Out of these, it was not possible to source two articles. The majority of the studies (68%) found did not give any reliability statistics. Four studies (Houpt, 1985b; Badalatay, 1990; Reeves, 1996 and Dallman 2001) used percentage as a measure of observer agreement and agreement ranged from 79 to 94%. Sams (1993) reported a Correlation Coefficient of 0.63 to 0.78 between two observers while Poorman (1990) had a Correlation Coefficient of 0.4 on the sleep scale and 0.8 on all the other parameters on Houpt. In a study to evaluate behavioural scales (Hosey and Blinkhorn, 1995) the authors achieved an agreement of K 0.77 for the Houpt Scale and an agreement of K 0.755 for the VAS. Personal communication with one of

authors reveals that there was little training and calibration of the observers done and they watched 19 hours of videotapes.

Nevertheless, it is noted that in the vast majority of sedation studies using observers to rate subject behaviour, there is no mention of training, calibration or reliability statistics. This fact begs the question: “why?” Four of the studies used only one observer for patient rating and therefore did not require inter-rater reliability however; there is no mention of intra-rater reliability. All the other studies had more than one observer but there seem to have been no training, calibration or reliability statistics carried out. It may be possible that this has been an oversight on the part of the authors and they forgot to mention the statistics for reliability or reliability scores where not undertaken or it may be that the reliability scores were so poor that the authors thought better of reporting them. In any case this is a shortcoming of sedation research in general.

As can be noted from the results, there is some missing data mainly at time-point one i.e. introduction to the nose-piece where the missing videos amount to almost a third of the sample. The reason for this amount of missing data is either because in these cases the video camera was switched on after the patients was seated on the chair and the introduction to the nose-piece had already been done or no introduction was performed by the operator because it was presumed that the child had already had an introduction at the sedation assessment clinic.

6.4.1 Reasons for poor observer reliability

In the present study each score on the scales was given a meaning so that the observers had an indication of what the researcher meant by the score. For example, a VAS score of 1 would indicate that though the subject is sitting on the chair s/he is

crying while a VAS score of 10 indicated that the subject is enthusiastic about treatment. The GRS scores were also given similar meanings and the Houpt scale which has already got a meaning for each score was left unchanged. The observers commented that the meanings appended to the scores on the VAS and GRS scales were close to each other and it was at times difficult to differentiate from one score to another. In view of this the meanings were slightly altered by the observers themselves during calibration. Despite this it did not seem to have improved their agreement. This is possibly because the calibration and the assessment of the study videos were done on separate occasions due to time constraints and therefore, the observers may have forgotten what behaviour they had previously associated with what score.

When there is a wide range of possible scores it is more difficult to achieve agreement. This is possibly why the dichotomous scale used for nose-piece acceptance had better agreement than the other scales which had five, eleven and seventeen possible scores in their ranges.

The observers also commented that at times the position of the video-camera, the patient or the tray-table on the dental chair made it difficult for them to be able to see and assess the subject's behaviour. There were also some videos in which the dental light was shining on the patient's face in such a way that it made it impossible to assess any facial expressions. Although the person setting up the camera ensured that the patient and the reservoir bag were always visible, the position of the patient and the operator as well as the equipment could change during treatment and the researchers were not present during the session to change the position of the camera. There were also times when staff passed in front of the video-camera obscuring the

view. It would have been ideal to have the video-camera positioned in a constant place relative to the chair in all the clinics however; this was not possible due to space constraints in the different surgeries.

Finally, the assessment of patient behaviour is very subjective and it is possible that the poor agreement is due to character differences between the observers. This should not be the case since the observers were calibrated on three different occasions. Ideally, the training and calibration should have been repeated until there was stronger agreement between the observers but time constraints prevented this.

6.5 HIGH RATE OF ACCEPTANCE OF THE NOSE-PIECE

Another reason why the pamphlet did not seem to make a difference could be the fact that there was already a high rate of acceptance of the nose-piece in the sample, therefore, leaving little or no room for improvement. Studies have reported that between 4% and 23.5% patients refuse to wear the nose-piece (Cooper *et al*, 1978; Major *et al*, 1981; Warren *et al*, 1983). A previous study carried out at the Glasgow Dental Hospital and School reported a rate of refusal of the nose-piece of 11% (Naudi *et al*, 2006). The rate of refusal in the present study was 2.9% of the total sample and 5.9% of the control group. It is possible that the high rate of acceptance of the nose-piece at this centre is because patients are familiarised with the equipment at the time of the sedation assessment clinic. They attended this prior to their sedation appointment irrespective of whether treatment occurred in the hospital or community clinics. Nevertheless, the rate of refusal in the present study is much lower than one would have expected when previous studies at this centre are compared (Busuttill Naudi *et al*, 2006). The reasons for this could be two-fold. Firstly, due to the long waiting-list for treatment, as a result of the refurbishment being carried out in the

department, only the patients keenest for treatment actually attended, and these would have been more likely to accept the nose-piece. Secondly, the patients in the present study were recruited from both the hospital and community dental service and it is possible that the patients seen in the community service might have been less anxious and therefore, they are more likely to accept treatment. This would have influenced the rate of acceptance compared to the results reported in 2006 since patients studied in that instance were only ones attending the hospital service.

6.6 POSSIBLE LIMITATIONS WITH PAPER-BASED COGNITIVE INFORMATION

6.6.1 *Patients might not have read the pamphlet*

It is possible that the patients did not actually read the pamphlet. The pamphlet was handed to the patient at their sedation assessment visit and at that visit the recruiter briefly went over the pamphlet with the patient. However, the patient was trusted to read the pamphlet at home and to learn and practice the exercises for use during treatment. It is not possible for us to know if the patients followed these instructions.

Furthermore, there is usually a waiting list for treatment and patients are not seen for treatment immediately after their assessment visit. It is possible that the patients and their parents shelved the pamphlet and then forgot about it when the treatment appointment actually arrived. A compounding factor was that during the period of the study, the Paediatric Dentistry Department at the Dental Hospital was undergoing major refurbishment and this prolonged the wait for treatment even further.

One possible way of ensuring that the pamphlet has been read is to provide a questionnaire after treatment which asks specifically about the pamphlet and its usefulness but which however, the subjects would not be able to complete unless they have actually read the pamphlet.

6.6.2 *Self-administered cognitive behaviour therapy*

Cognitive behaviour therapy is traditionally administered by a therapist in individual or group formats over a number of sessions. Recently studies have shown that CBT can be successfully self-administered over the internet. A systematic review by Cuijpers *et al* published in 2007 found that the effects found for Internet interventions targeting pain and headache were comparable to the effects found for face-to-face treatments. A meta-analysis of internet-based CBT for anxiety and depression concluded that internet-based interventions especially those with therapist support are effective (Spek *et al*, 2007). In the paediatric population, Spence *et al* (2006) have shown that the Internet delivery of CBT sessions for child anxiety disorders is feasible and may provide a valuable adjunct to clinic-based treatment. In this study the internet-administered sessions were adjunctive to clinical sessions and therefore the patients still had therapist support.

It was not possible to find any literature regarding the delivery of CBT via pamphlets. Interestingly, in a previous study conducted at this unit evaluating a computer package and a paper-based package as preparation for children undergoing dental general anaesthesia, it was found that the paper-based package was not as efficacious in facilitating coping behaviour (Campbell *et al*, 2005). The authors postulate that this may be because the paper-based package provided information overload for the patients. It is possible that this was also the case in the present study. It may be that there were too many exercises in the pamphlet for the subjects to learn especially since they were not assisted by a therapist.

6.6.3 Adult only evaluation of the pamphlet

Although it was originally intended to have a focus group of paediatric patients to evaluate the pamphlet, this proved to be unfeasible. Therefore, the final pamphlet was based on evaluation by a focus group of clinicians thus giving us only an adult perspective of the suitability of a pamphlet created for children. This may have resulted in a pamphlet that might not have been fully adapted to the paediatric population. It is known that children's use of language differs from that of adults and that children may have problems in comprehension therefore leading to discrepancies between the child's and the researcher's understanding (Marshman *et al*, 2008). Therefore, it is possible that since the pamphlet was developed and evaluated by adults, the language used might have not been fully comprehensible to a child and as such the subjects may not have fully appreciated the content of the pamphlet.

6.7 THE HAWTHORNE EFFECT

Finally it may also be possible that there was some element of the Hawthorne Effect, meaning that all the patients performed well during their treatment because they knew that they were being observed (McCarney *et al*, 2007). All the patients had to be made aware that their treatment sessions were going to be filmed so that they could consent to this and the video camera was in the clinic where it was fully visible by the patient.

6.8 FUTURE STUDY

In order to improve the quality of the results, a few changes should be made to the research strategy should a future study be planned.

- Focus group of paediatric patients to evaluate the pamphlet

- Larger sample size
- Single operator for all sessions
- Ensuring patients have actually read the pamphlet
- Enlisting the help of a psychologist in administering CBT
- Making the video-camera invisible to the patients or avoiding filming altogether

6.9 CLINICAL IMPLICATIONS OF THE STUDY

Policy documents such as the UK Children's National Service Framework and Improving oral health and Modernising NHS dental services in Scotland urge professionals to improve delivery of services for children. The underlying rationale for undertaking the present study was to see if it is possible to increase the success of inhalation sedation by making it easier for paediatric patients to accept this modality of treatment. Should this have proved to be successful then we would see a further reduction in dental treatment with general anaesthesia as well as a reduction in dental anxiety and possibly improvement in oral health.

Chapter 7

Conclusion

7.1 PRIMARY CONCLUSION

This randomised controlled single blind study established that a cognitive exercises pamphlet was not successful at improving child patient compliance with acceptance of the nose-piece used for the provision of inhalation sedation.

7.2 SECONDARY CONCLUSION

This randomised controlled single blind study established that a cognitive exercises pamphlet was not successful at improving child patient behaviour during treatment with inhalation sedation.

7.3 THE NULL HYPOTHESIS

“The cognitive pamphlet does not help paediatric dental patients cope better with inhalation sedation”

The Null Hypothesis is accepted.

Appendices

Appendix 1
Inhalation sedation retrospective study data collection sheet

Date of first IS visit:

Patient number:

Patient initials:

Patient Age:

Patient gender:

Partial postcode:

Number of IS appointments attended:

Total number of IS appointments made:

Appendix 2

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Augmented information to aid dental treatment under inhalation sedation

Name of Researcher: Antoniella Naudi

Please tick box ()

1. I confirm that I have read and understand the information sheet dated: 13.05.2006, (Version 2). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of any of my dental notes and data collected during the study may be looked at by responsible individuals from Glasgow Dental Hospital and School. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.

Name of Patient

Signature

Date

Name of Parent

Signature

Date

Name of Person taking consent
(if different from researcher)

Signature

Date

Researcher

Signature

Date

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in dental notes
(Date: 13.05.2006 Version 2)

ASSENT FORM FOR CHILDREN

Project title: Augmented information to aid dental treatment under inhalation sedation

Researcher: Antoniella Naudi

Child (or if unable, parent on their behalf) /young person to circle all they agree with please:

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

Have you had your questions answered in a way you understand? 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 any answers are 'no' or you **don't** want to take part, **don't** sign your name!

If you do want to take part, please write your name and today's date

Your name _____

Date _____

Your parent or guardian must write their name here too if they are happy for you to do the project

Print Name _____

Sign _____

Date _____

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

Print Name _____

Sign _____

Date _____

Thank you for your help.

(Date: 13.05.2006 Version 2)

Parent/Guardian Information Sheet

Title of Project: Augmented information to aid dental treatment under inhalation sedation

Dear Parent/Guardian

Your child is being asked to take part in a study, which will be carried out at the Paediatric Dentistry Department, Glasgow Dental Hospital and School.

All the children who come for dental treatment with inhalation sedation usually receive an information sheet. This information sheet explains what inhalation sedation is and how it works. We have made another leaflet with some simple exercises (10.05.2006/Version 1) which children can practice at home and then use when they come back for dental treatment.

The purpose of the study is to assess whether this extra information leaflet distributed to children before their dental treatment under inhalation sedation will help them behave differently during dental treatment.

A group of children will be given this leaflet while another group will not. Your child will be randomly assigned to one of the groups by a computer. The first treatment session under inhalation sedation that your child attends for will be video-taped. The video-tapes will then be studied to see whether children who get the information leaflet behave differently during dental treatment. The video-tapes will be kept in a safe place and they will be destroyed at the end of the study. It will not be possible to identify your child from the research results. The project has been approved by an Ethics Committee.

All the children attending for treatment under inhalation sedation will be asked whether they wish to take part in the study. We hope to have a total 120 children in the study. It is up to you and your child to decide whether or not to take part. You are free to withdraw from the research at any time and without giving a reason. Your decisions about this will not affect the standard of care your child will receive.

If you and your child are happy to take part, and are satisfied with the explanations from your research team, you will be asked to sign a consent form. A copy of the consent form will be given to you for your records.

Thank you for your help

Antoniella Naudi
Researcher

(Date: 13.05.2006 Version 2)

Adolescent Information Sheet

Title of Project: Augmented information to aid dental treatment under inhalation sedation

We are asking you to take part in a study, which will be done in this department.

All the teenagers and children who come for dental treatment with inhalation sedation usually receive an information sheet. This information sheet explains what inhalation sedation is and how it works.

We have made another leaflet (10.05.2006/Version 1) with some simple exercises which teenagers can practice at home and then use when they come back for dental treatment.

We are doing the study to see if this extra leaflet will help teenagers behave differently during dental treatment.

A group of children and teenagers will be given this leaflet while another group will not. A computer will choose which one of the groups you will be in. Your first treatment session with inhalation sedation will be video-taped. The video-tapes will then be studied to check if children and teenagers who get the information leaflet behave differently during dental treatment. The video-tapes will be kept in a safe place and they will be destroyed at the end of the study. It will not be possible to identify you from the research results. The project has been approved by an Ethics Committee.

All the children and teenagers attending for treatment under inhalation sedation will be asked whether they wish to take part in the study. We hope to have 120 children and teenagers in the study. It is up to you to decide whether or not to take part. You are free to stop from the research at any time. You do not have to give a reason if you decide to stop. Your decisions about this will not affect the standard of care you will receive.

If you have understood what we have told you and you are happy to take part, then we will ask you to sign a consent form. A copy of the consent form will be given to you for your records.

Thank you for your help

Antoniella Naudi
Researcher

(Date: 13.05.2006 Version 2)

Child Information Sheet

Title of Project: Augmented information to aid dental treatment under inhalation sedation

We are asking you to take part in a study, which will be done in this clinic.

We have made a leaflet which has a set of exercises (10.05.2006/Version 1) that children can practice at home and then use when they come back for dental treatment.

We want to find out this will help children be less worried about going to the dentist.

How will this study be done?

A group of children will be given the leaflet while another group will not. You will be put in one of the groups by a computer. The first time you come back to have your teeth fixed you will be video-taped. The video-tapes will then be studied to see if the children who get the leaflet are less nervous.

Who will be asked to be in the study?

All the children coming to this clinic will be asked if they wish to be in the study. You do not have to be in the study if you do not want to. If you want to be in the study your mum/dad will sign a paper to say that you want to be in the study.

Thank you for your help

Antoniella Naudi
Researcher

(Date: 13.05.2006 Version 2)

Appendix 3

**INHALATION SEDATION
FOR CHILDREN**

**GLASGOW DENTAL HOSPITAL & SCHOOL
378 SAUCHIEHALL STREET
GLASGOW
G2 3JZ**

Telephone ; 0141 211 9670
Fax ; 0141 211 9800

Our aim is to make Children's Dentistry as comfortable and as easy as possible.

Many children that are referred to us are anxious about receiving dental treatment.

What is Inhalation Sedation ?

Inhalation sedation has been used in dentistry for almost 40 years. The therapy involves breathing a mixture of oxygen and nitrous oxide (laughing gas) through a cup that fits over the nose. The mixture of gases is then carefully adjusted until the child is relaxed, but not asleep. The aim of inhalation sedation is to produce sedation and relaxation, but not sleep. Therefore the child is awake and aware of all the people, surroundings and subsequent dental treatment at all times.

Can any child have Inhalation Sedation ?

Inhalation sedation is a very safe technique for most children. We will thoroughly check that your child is suitable to have Inhalation sedation .

If there are any changes in their medication or health status let us know. Your child will have to be able to breathe through their nose and so if he/she had a cold we may have to postpone this particular type of treatment until he/she has recovered.

Is Inhalation Sedation Safe ?

For the patient – Yes.

Scavenging equipment is used to reduce nitrous oxide pollution in the surgery, mostly for the benefit of the dentist and assistant.

Will the tooth still need to be numbed ? Will a local anaesthetic (jag) still be necessary ?

Yes. Our aim is to always ensure that treatment is comfortable and acceptable. Inhalation sedation is used as part of a process involving the gradual introduction to various dental procedures. Therefore, through the course of treatment your child will become less anxious and should become ready to accept a local anaesthetic.

Are there any special instructions before treatment ?

- Eat and drink normally but avoid a particularly heavy meal. (A light meal such as tea and toast is acceptable).

- The child must always be accompanied by a parent, an adult or guardian. The parent or guardian does not need to stay with the child during the whole treatment session. Often the child prefers their parent or guardian to wait in the waiting room.
- The parent or guardian will be asked to sign a consent form.
- Try to avoid bringing other children with you as they can be a distraction to the anxious child.

How you can help in the treatment of your child.

The service that we offer is time consuming not only for us, but for parents and children alike. Therefore we would like to draw your attention to the importance of prevention of further dental disease and future anxiety.

Here are some of the steps that you can take at home to alleviate your child's anxiety and reduce the need for lengthy dental procedures.

- Prevent tooth decay by cutting down on the number of sugary snacks and drinks taken between meals.
- Prevent gum disease and tooth decay by brushing teeth efficiently with a small amount of fluoride toothpaste at least twice a day.
- Try to avoid 'building-up' the child before the visit with such things as stories and jokes about *the dentist* from other adults and children.
- Try to show the child YOU are not nervous (*even if you are!!*).

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Abstract

The qualitative evaluation of a cognitive pamphlet

A Busuttill Naudi, T Musiello, MT Hosey International Journal of Paediatric Dentistry 2007; 17(Suppl 2): 22, Annual Scientific Meeting BSPD: London 2007

Introduction

A pamphlet was designed to appeal to 7-16 year-old patients referred for dental treatment with inhalation sedation in liaison with a psychologist. It was produced using Microsoft Publisher 2003 in a 3-panel brochure format.

Objective

The aim of the qualitative evaluation was to ensure that the pamphlet designed was suitable to use with paediatric patients.

Sample and Methods

The pamphlet was evaluated by healthcare professionals, mainly paediatric dentists. The evaluation was designed as a one-to-one structured interview using a questionnaire led by the main researcher. The Gunning Fox Index was used to assess the readability of the pamphlet.

Results

The results of the structured interviews indicated that the pamphlet was generally found to be appropriate for the cohort of patients it was intended for. However, there were a few issues that needed to be addressed. The readability age of the cognitive package was found to be approximately 5 years.

Conclusions

Changes were made in the pamphlet to reflect the suggestions of the focus group interviewed.

The use of a cognitive pamphlet to improve cooperation with inhalation sedation

Busuttill Naudi A, Sherriff A, Hosey MT International Journal of Paediatric Dentistry 2009; 19(Suppl 2): 1, Annual Scientific Meeting BSPD: Birmingham 2009

Background: Nitrous oxide inhalation sedation is a highly successful technique for helping anxious patients cope with dental treatment. However, it still requires a certain amount of cooperation which some patients lack. Research shows that it is possible to teach children how to use cognitively oriented coping strategies. **Aim:** To develop and evaluate a cognitive pamphlet to help facilitate inhalation sedation treatment for anxious paediatric dental patients. **Method:** the overall approach was a single blind randomised controlled clinical evaluation. Subjects were assessed and recruited to the study from sedation assessment clinics and randomly allocated to either a control or a study group. The subjects in the study group received a previously developed pamphlet consisting of cognitive behavioural therapy exercise. All the subjects had their first treatment visit videotaped and all the tapes were watched by two blinded observers at the end of the study and the subjects' acceptance of the nose-piece as well as their overall behaviour was scored using the Houpt Scale, the Visual Analog Scale and the Global Rating Scale at four time-points. The primary outcome measure of the study was whether the pamphlet improved subject acceptance of the nose-piece. The secondary outcome measure was the overall behaviour of the subjects during treatment. **Results:** The final number of subjects participating in the study was 35. The preoperative anxiety scores were very similar for both groups. There was no statistically significant difference between the groups for either the primary or the secondary outcome measures. **Conclusion:** The pamphlet was not successful in improving subject cooperation with inhalation sedation.

Published paper

An inhalation sedation patient profile at a specialist paediatric dentistry unit: a retrospective survey.

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Abstract

Aims: To report on the characteristics, treatment, attendance, scheduling and duration of treatment sessions of child patients attending a specialist paediatric dental hospital service for inhalation sedation. **Method:** A retrospective study was carried out of all 88 patient case notes of inhalation sedation recipients between September 2004 and March 2005. The recorded data included: child's age, gender and the level of social deprivation together with the details of the treatment that was undertaken, the time between the first and the current/last sedation appointment and the total number of appointments attended, cancelled and missed. **Results:** Twenty of the subjects were excluded giving a sample of 68; 51% male, mean age at start of treatment of 9.8 years (range 4 to 15) and mean age at end of treatment 10.6 years (range 4 to 16). Of these children 35 (51%) were socially deprived. In respect to treatment, 29% had extractions, 22% endodontics, 81% restorations and 25% fissure sealants. In respect to the number of quadrants that had teeth requiring treatment; 26.5% had one, 25% two, 22% three and 26.5% had four. The mean number of treatment sessions required was 4.4 with a mean duration between first appointment and last appointment of 9.5 months (range: 0.25-51). There were 27% of appointments cancelled, while 12% of patients failed to keep their appointment. **Conclusions:** Although over half of the children treated under inhalation sedation, came from social deprived areas attendance was reasonable and the majority required less than 5 appointments for treatment completion. The treatment provided was variable not only in respect to the procedures but also to the number of quadrants treated.

Introduction

In the United Kingdom (UK), there has been an over-reliance on general anesthesia (GA) and the government has tried to reduce this and recommended that conscious sedation or relative analgesia (RA) and local analgesia (LA) should replace GA wherever possible [Department of Health, UK, 1990; Department of Health, 2000] and so various authors have favoured the increased use of RA and LA instead of GA [Blain and Hill, 1998; Crawford, 1990; Shaw et al, 1996; Shepherd and Hill, 2000].

The nitrous oxide inhalation sedation (RA) technique involves a controlled mixture of nitrous oxide and oxygen and this has been used as a patient management technique in UK dentistry since the 1940s [Shaw et al., 1996; Shepherd and Hill, 2000]. RA has been reported to have an extremely low incidence of patient morbidity [Jastak and Paravecchio, 1975; Duncan and Moore, 1984] and has none of the mortality risks associated with GA [Roberts et al., 1979]. Various studies have documented the success of RA for the provision of dental treatment [Warren et al., 1983; Bryan 2002] especially for orthodontic extractions [Shaw et al., 1996; Shepherd and Hill, 2000]. The mean age of the patients treated in these studies ranged from 7.2 to 11.9 years.

The provision and the demand for GA for dental extractions in children have reduced in the UK [Shaw et al., 1996] and in Scotland [National Audit for Scotland, 2002]. Furthermore, the mean age of the children referred for GA has also gradually reduced [Grant et al., 1998] and there is a suggestion that referral for GA extraction is related to a need for multiple and multi-quadrant extractions [Macpherson et al., 2005]. Despite these changes it is not known if this has led to an expansion of the RA service provision, not only to include these children who might otherwise have been referred for GA extractions, but also those who require restorations. However, there have been no contemporary studies reporting the characteristics of the children undergoing RA in the UK.

The most common reason for referral of patients to specialist paediatric dentistry clinics is the management of behaviour problems [Shaw et al., 1994; Evans et al., 1991]. This is a challenge to dentists and can be a burden on dental services; especially when attendance is poor [Klingberg et al., 1995]. There are no recent studies to show the attendance pattern and treatment duration in this potentially new cohort of patients requiring RA in the UK.

The aims of our audit were to report:

- 1 on the characteristics and treatment of child patients attending a Specialist Paediatric Dental Hospital Service for inhalation sedation
- 2 on attendance of the child patients and the scheduling and duration of the treatment sessions.

Key words: Child anxiety, inhalation sedation

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Materials and methods

A retrospective descriptive study examined the case notes of all 88 child patients treated under RA over a six-month period between September 2004 and March 2005 at the Child Dental Health Department, Glasgow Dental Hospital and School (GDH&S). The specialist RA service at GDH&S accepts referrals from both general dental practitioners (GDPs) and Community Dental Services (CDS). Referral is usually due to anxiety or refusal of treatment under LA. The anxious patients are first screened on a consultant (specialist) new patient clinic; this is generally followed by a course of appointments for prevention and simple behaviour management, such as an introduction to the use of a hand signal, positive reinforcement and familiarisation with the department environment, prior to scheduling on a pre-sedation assessment clinic. This pre-sedation assessment clinic is where the treatment options are discussed again with the child and parent and if the RA technique is selected as the best option (this service also offers intravenous sedation and oral rehabilitation under GA, consent for RA treatment is obtained and the nasal mask is introduced. This clinic is run by one of the consultants (MTH). This assignment of anxious children for treatment under RA, intravenous sedation or GA is subjective and is dependant on their perceived (not measured) level of anxiety and dental needs by the consultant. A wide variety of patients are treated on the RA service and the criteria are based on the UK national clinical guidelines [Hosey, 2002]. Following these introductory visits for behavioural management and pre-sedation assessment, the patient is then given an appointment on any of the five RA clinics that are run in the department every week. A maximum of 15 patient sessions are scheduled per week. These RA sessions are carried out by one specialist (consultant), three senior house officers (junior specialists) and a post-graduate (Masters) student respectively.

The demographic details recorded were: age, gender and partial postcode. This partial postcode was used to calculate the level of social deprivation based on the Carstairs Index [McLoone, 2004]. This index provides DEPCAT (social deprivation category) scores ranging from 1 to 7 with 1 being the most affluent area and 7 the most deprived area and is a common method for reporting the level of deprivation for use in Scotland [McLoone, 2004]. Type of treatment undertaken, the maximum number and the average number of restorations and extractions carried out per patient and the number of quadrants treated (this did not include pre-sedation sessions or post sedation treatment with local anaesthesia) was also retrieved from the case notes. The data was coded to ensure patient anonymity.

The type of treatment undertaken was then further divided into the number of: further acclimatisation sessions under RA; fissure sealants; restorations; endodontics and extrac-

tions. In respect to the restorations, this was further subdivided into the number of single-surface and multiple-surface restorations and the type of restorative material used was recorded. During the RA acclimatisation sessions patients did not receive operative dental treatment but further experienced RA and, if cooperation allowed, had prophylactic dental polishing. This RA acclimatisation session was only undertaken in cases of severe anxiety, and usually only at the first RA appointment.

Data relating to the time lapse between the first and the last appointments required for treatment completion and the number of appointments attended, failed and cancelled, was collected. Failed appointments were considered to be those appointments for which the patients did not attend and gave no prior warning to the department. Cancelled appointments were those that the department had prior notification of. Parents had previously been instructed to give at least 48 hours notice prior to cancelling appointments.

Results

Twenty of the 88 originally identified subjects were excluded for the following reasons; one set of case notes was not available for the study, four patients never attended for treatment, five patients were treated with LA alone and ten patients refused treatment with inhalation sedation and subsequently underwent treatment under GA or intravenous sedation. This left a final study sample of 68 patients. The mean age at the start of treatment was 9.8 years (range 4 to 15 years) and by the end of treatment the mean age was 10.6 years (range 4 to 16 years); 35 (51%) were boys. There were 14 (20.6%) children in the primary dentition, 16 (23.5%) in the mixed dentition and 38 (55.9%) in the permanent dentition. Thirty-five (51%) of patients came from socially deprived areas of the city (DEPCAT 5, 6 & 7). The 20 patients that were excluded from the study had similar characteristics as the patients that were included.

Various types of treatment were provided for patients under RA, these are further detailed in Figure 1. Treatment included non-invasive management such as acclimatisation sessions, provided to 25 (37%) of the children, and fissure sealants placement in 17 (25%). Extractions were necessary for 20 (29%) of subjects with a total of 34 teeth extracted; 26 of which were primary teeth; 29 of the total number of teeth extracted were due to caries. The majority of patients, 55 (81%), received restorative dental treatment. Of the total number of restorations carried out, 176 (71%) were single surface restorations, 64 (25.8%) were multiple surface and 8 (3.2%) were pre-formed metal crowns. Composite resin was the restorative material used most frequently (47% of all restorations provided) followed by amalgam (32% of all restorations provided) (Figure 2). The temporary dressings that made up 15% of the total number of restorations provided were either

used to seal access cavities in between endodontic visits or to dress permanent teeth of poor prognosis.

Endodontics was required by 20 (22%) of the children with a total of 23 teeth. The different types of endodontic procedures carried out under RA are detailed in Figure 3. All three of the non-vital pulpotomies and one vital pulpotomy were carried out in primary teeth. One vital pulpotomy and all the pulp cappings, pulpectomies and complete root canal treatments were carried out on permanent teeth. Three of the patients requiring permanent tooth pulpectomy had the remaining stages of the endodontic therapy carried out without the use of RA.

A representation of the average and maximum treatment received by patients overall in the various treatment categories is shown in Figure 4. In each session, for each patient the maximum number of quadrants treated was as follows; 49 patients had treatment in one, 18 in two, and one in three. None of the patients had all four quadrants treated in one session. Overall, one quadrant was treated in 18 (26.5%) patients, two in 17 (25%), three in 15 (22%) and four in 18 (26.5%) children. Within this sampling frame, 30 patients had completed their treatment and 38 were still continuing treatment under RA.

The mean number of total appointments required, including those failed or cancelled was 7.3. The mean number of total treatment sessions required, excluding failed or cancelled, was 4.4 and the mean duration of treatment was 9.5 months. There were 27% of appointments cancelled and 12% of patients failed to keep their appointments. These parameters are further demonstrated in respect to level of social deprivation in Table 1.

Discussion

This sample of patients was older than that reported previously in the UK and there are more boys [Blain and Hill, 1998; Crawford, 1990; Bryan, 2002]. It is possible that as young children in the West of Scotland have extensive dental caries [Pitts, 1998], they are likely to have previously undergone GA extractions. The mean age of children referred for GA extractions in Scotland is 6.7 years [Macpherson et al., 2005]. As over half of subjects in the present survey came from socially deprived backgrounds a high level of dental disease was not unexpected [Pitts, 1998]. The level of deprivation in the children in this sample reflects that in the Greater Glasgow NHS Health Board catchment area where DEPCAT scores 5, 6 & 7 make up 58% of the population and DEPCAT score 7 alone contributes 30% [McLoone, 2004]. Thus the proportion of socially deprived children treated with RA in the present study is similar to the proportion of socially deprived children living locally.

In a study by Veerkamp et al, [1991], all the patients had one session of acclimatisation and this could be repeated on the

second visit at the discretion of the operator. In the present study, all patients attended for a behaviour management session prior to attending the sedation assessment clinic. This may be the reason why only one third required further acclimatisation sessions under RA.

Various studies have reported the successful use of RA for dental extractions [Blain and Hill, 1998; Cooper et al., 1978; Crawford, 1990; Shaw et al., 1996; Shepherd and Hill, 2000]. In the present study, RA was used to facilitate the provision of a variety of dental treatments, but the majority of these were restorative. This proportion in the present study was slightly higher than previously reported in a similar retrospective study, although this earlier study was not limited to children [Hallonsten et al., 1983]. It should be noted that pulpectomies are now performed instead of non-vital pulpotomies in primary teeth but the former are included in the present study as this change occurred within the sample time frame.

Dental extractions were mostly carried out for caries rather than for orthodontic reasons but these were less common than an earlier similar retrospective UK study [Bryan, 2002]. This is probably due to the fact that patients requiring dental extractions only, e.g. orthodontic, are referred for treatment under RA to the Oral Surgery Department. Almost half of the sample required treatment in three or four quadrants highlighting the high treatment need of this group of patients and suggesting that even children with caries in multiple quadrants can manage without recourse to GA.

The mean number of appointments necessary for completion of treatment is similar to that quoted by Warren et al, [1983] and Veerkamp et al, [1991] but more than that given by Bryan [2002]. The reasons for a higher number of treatment visits in the present study may be because a third of child patients received further acclimatisation under RA. It is also possible that the cohort of patients treated in the present study was more anxious than those reported by Bryan [2002] which was based in the CDS rather than a Hospital Dental Service but anxiety levels were not recorded in either of these studies. Furthermore, the treatment need for the children in this sample was extensive; half required treatment in three or four quadrants and junior staff, rather than paediatric dentistry specialists, largely provided the treatment.

In the present study the duration of treatment was lengthy, possibly explained by the 12% failure and 27% cancellation rates, which has significant cost implications. No references to the rate of failed and cancelled appointments have been found in the literature in relation to RA. However, a study carried out by Richardson [1994] reported a 13.6% failure rate at an academic orthodontic clinic over a six-month period. Social deprivation has been quoted as having a negative effect on attendance for dental treatment [Can et al., 2003]. Patients who are offered treatment under RA sedation in our department are usually given block appointments in consecutive weeks. This system is thought to be helpful for these

patients because in this way they do not have to wait long between treatment appointments thus decreasing the possibility of tension build-up.

Out of the original sample of 88 patients, four never attended for treatment and ten refused treatment with RA. Those who refused to have treatment with RA did so because they were not cooperative enough to attempt treatment with the nosepiece despite having been introduced to this at the previous sedation assessment visit. These 14 patients were considered a failure because it was not possible to carry out the necessary treatment under RA and referral for treatment using other pharmacological techniques was necessary. Thus, the 84% success rate for RA compared well with other studies [Warren et al., 1983; Bryan, 2002; Blain and Hill, 1998]. If this service was not provided these patients would either have had their dental treatment performed under a high degree of psychological stress and discomfort or would have needed GA [Hallonsten et al., 1983].

A limitation of this study is that the level of dental anxiety was not measured. Anxiety levels are not recorded as a matter of routine during assignment of patients for dental treatment aided by pharmacological techniques and so there was no data available for this retrospective study. However, the service is a secondary and tertiary service and accepts referrals of anxious children who have not been able to cooperate for treatment elsewhere. All the patients in this study had not been able to accept treatment in the referring primary dental service. Future studies should include an assessment of anxiety and ideally be should performed in a primary care service where treatments can be controlled so that the findings could be more easily compared to controls who are having the same treatment but do not require RA.

A major problem that faces the RA service at Glasgow Dental Hospital and School is the high rate of failed appointments. Studies have shown that both postal [Can et al., 2003] and telephone [Lindauer et al., 1993] reminders can reduce the failure rate, as can minor modifications to appointment cards [Patel et al, 2000]). However, it was also shown that the use of a postal reminder does not counteract the effect of social deprivation on failure rates [Can et al., 2003]). Ways of decreasing the failure rate at the inhalation sedation service are currently being explored.

Conclusions

Although over half of the children treated under inhalation sedation, came from socially deprived areas attendance was reasonable and the majority required less than 5 appointments for treatment completion. The treatment provided was variable not only in respect to the procedures but also to the number of quadrants treated.

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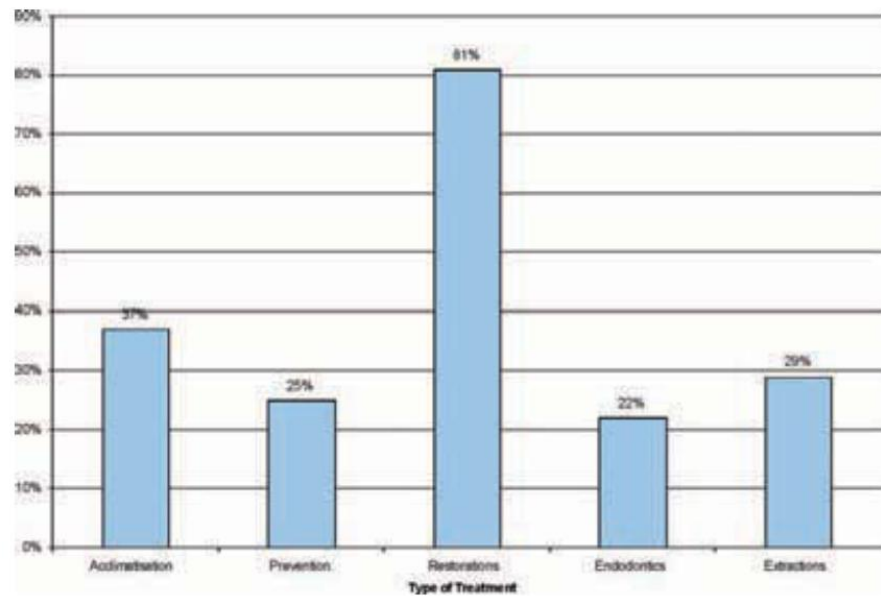


Figure 1 Percentage of patients receiving the various types of treatment under inhalation sedation in a study of children treated under RA in Glasgow, Scotland.

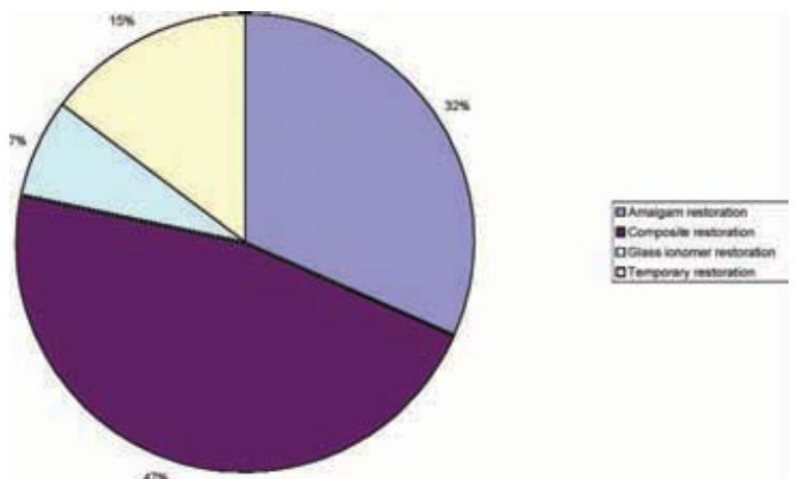


Figure 2 Percentage value of the different types of materials used for restorations carried out under inhalation sedation in a study of children treated under RA in Glasgow, Scotland.

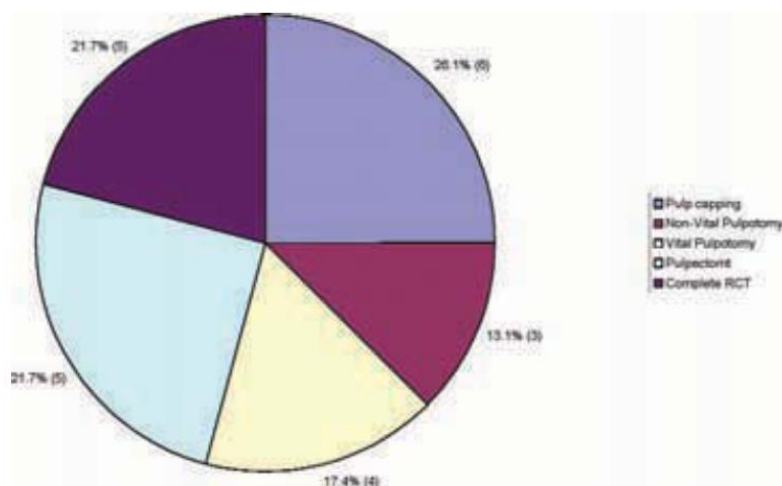


Figure 3 Percentage (number) of different type of endodontic procedures carried out under inhalation sedation in a study of children treated under RA in Glasgow, Scotland.

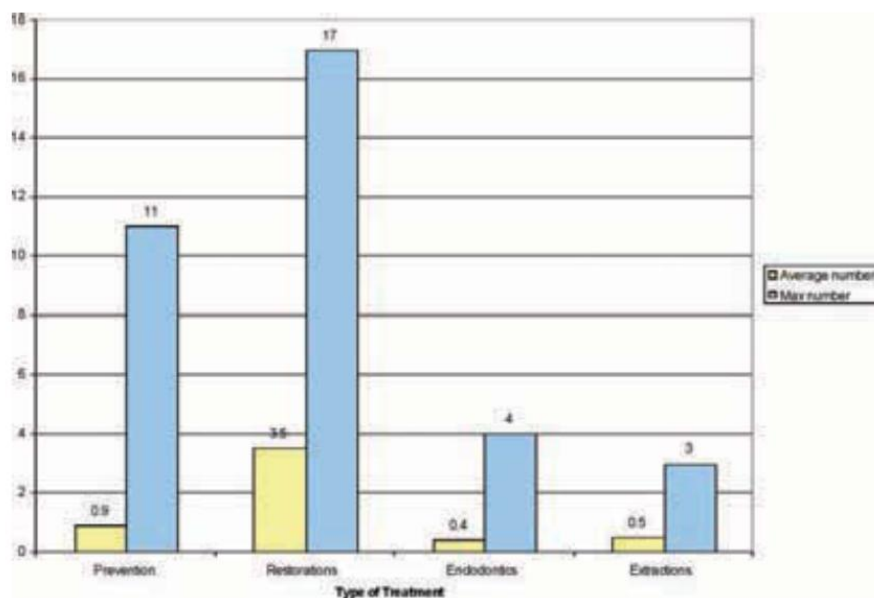


Figure 4 Average and Maximum number of treatment carried out per patient in a study of children treated under RA in Glasgow, Scotland.