# INVESTIGATING HYPNOSIS FOR THE ALLEVIATION OF DENTAL ANXIETY DOES THE ADDITION OF HYPNOSIS TO INHALATION SEDATION REDUCE DENTAL ANXIETY MORE THAN INHALATION SEDATION ALONE

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## SCHOOL OF DENTISTRY

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## Abstract

University of Manchester - Catherine Potter - Doctor of Philosophy

### INVESTIGATING HYPNOSIS FOR THE ALLEVIATION OF DENTAL ANXIETY - DOES THE ADDITION OF HYPNOSIS TO INHALATION SEDATION REDUCE DENTAL ANXIETY MORE THAN INHALATION SEDATION ALONE

28th November 2013

Chapter 1 reviews the literature. It gives a historical overview of hypnosis. It reviews the literature on dental anxiety, including its prevalence and aetiology. It reviews behavioural and cognitive behavioural treatments of dental fear. Inhalation sedation its mechanism of action, effectiveness and draw-backs are discussed. The literature on hypnosis is selectively reviewed, its use in anxiety and dentistry and lastly, the combination of sedation techniques, particularly IHS, is discussed. It is concluded that evidence for the use of hypnosis for the alleviation of dental anxiety needs to be critically addressed.

Chapter 2 presents the published protocol of a Cochrane systematic review followed by qualitative results of this review. 11 studies of generally poor quality were included in the review which concludes that there are significant problems with the evidence due to methodological issues, the different outcome measures used and the generally high or unclear risks of bias. There is some evidence that hypnosis may help patients who have a normal range of dental anxiety but who are undergoing a stressful dental procedure. Studies of phobic patients were characterised by high levels of drop-out behaviour and hypnosis could not be shown to be superior to other forms of behavioural treatment.

Chapter 3 describes two studies which aimed to develop a Mood Induction Procedure to induce temporary dental anxiety in volunteers. This was used in two later studies. A non-clinical sample was used as a 'proof of concept' study was desirable. Study 1tested excerpts of a film, producing only a medium rise in anxiety (ES r = .49). The second study used a shorter, more concentrated film. This produced a large increase in anxiety (ES r=.86). Heart rate was investigated as a possible physiological measure of anxiety, but was not found useful.

Chapter 4 describes two randomised controlled studies aiming to investigate whether hypnosis combined with IHS would reduce the anxiety produced by the film more than a control procedure in which IHS was combined with the reading of a story. These studies suggested there may be some effects attributable to hypnosis, but conclusive benefit was not demonstrated.

Chapter 5 presents discussion and the overall conclusions of the thesis. Conclusions include the need for further well designed large scale trials involving hypnosis.

## Declaration

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# **CHAPTER 1**

# **Literature Review**

## **Historical Background**

Both hypnosis and nitrous oxide have been proposed to be the answer to the control of pain in dentistry for over 200 years. Before the discovery of the analgesic properties of nitrous oxide, practitioners of what was then known as 'mesmerism' were claiming to be able to eliminate the pain associated with dental extractions (Chaves, 1997) and many other surgical procedures (Gauld, 1992). At the time, these claims were met by scepticism in the medical establishment as can be seen by the letters pages and discussion pieces in the Lancet (1829, 1846). The controversy is not resolved today as some believe that these historical case reports are evidence that profound anaesthesia, sufficient for surgery to be carried out, was commonly achieved (Gauld, 1992) whereas others are more cautious (Spanos and Chaves, 1989). Ultimately, mesmerism was displaced by the advent of chemical anaesthesia, but for a time the outcome of the debate between the two was in some doubt (Chaves, 1997) as both mesmerism and nitrous oxide had well publicised failures as well as successes, including Horace Wells' infamous demonstration of the use of nitrous oxide for a tooth extraction (Malamed, 1995). In addition, ether, nitrous oxide and mesmerism were associated with recreational use and so had poor reputations.

In the early days, chemical anaesthesia, mainly using ether and chloroform, was extremely dangerous with reports of fatalities increasing in proportion to the increase in use (Malamed, 1995). Nitrous oxide had fallen into disuse following Wells' failed demonstration and the difficulties involved in its manufacture, until it was shown to be successful and safe by Gardner Quincey Colton, who by 1881 had documented 121,709 cases of nitrous

oxide anaesthesia in dentistry, with no deaths, despite the fact that he used 100% nitrous oxide (Malamed, 1995 p. 191).

Despite the advent of chemical anaesthesia, some dentists continued to use hypnosis and an early account of a combination technique has been reproduced recently (Schupp, 1997). This dentist, writing in 1894, describes his treatment of a patient who had experienced two failed attempts to extract a tooth using nitrous oxide anaesthesia. He initiated ether anaesthesia, but removed the mask before anaesthesia was established. He then ordered the patient to repeat the phrase "I am already fast asleep". Schupp reports that at this point, the patient lost the cyanosis from his face and accepted verbal suggestions that he would open his mouth when he touched his upper lip and that he would give him a peach to eat and that when he woke up in exactly two minutes, he would feel well and remember eating the peach. When the tooth was extracted and the patient awake, he apparently believed that the tooth in the forceps was a peach stone. Schupp reports using this procedure a further nine times, with only one partial failure and went on to assert the advantages of hypnosis to be that when it is used correctly "one does not need to fear a lethal outcome ... (and) it is safe to use hypnosis even when anaesthesia is absolutely contraindicated..." (p.110). Langa (1968) describes the periods of renewed interest in nitrous oxide for analgesia in 1913-1918 and 1932-1938 and the following loss of interest due to poor results. He attributes this to the erroneous idea that high concentrations of nitrous oxide could eliminate the pain of dental treatment, rather than reduce fear and anxiety. This is paralleled by dentists having false expectations of hypnosis as they expect to be able to use it instead of

chemical local anaesthetics (Chaves, 1997). Langa began teaching postgraduate courses in relative analgesia in 1949 and had taught more than 6000 dentists in the US (Malamed, 1995).

In Britain, sedation use increased in the recent past, and a survey of dentists in 1989 revealed that 65% had postgraduate training in inhalation sedation, 50% in intravenous sedation and 47% in hypnosis (Edmunds and Rosen, 1989). However, it seemed that the techniques were used much less often than 'patient management' and general anaesthesia. A later survey aimed to discover what methods were used for anxious patients and reasons for not using them and discovered that many dentists did not feel confident, did not have enough time or had not received enough training in both sedation and psychological techniques including hypnosis (Hill et al., 2008).

In 1990 the Poswillo report was published. This was the report of an expert working party prepared for the Standing Dental Advisory Committee of the Department of Health. It considered the need for the use of general anaesthesia and sedation in dentistry outside hospitals and to develop guidelines for their safe use (Poswillo, 1990). This report began the process of removing general anaesthesia from general dental practice which was completed in 2000 when 'A Conscious Decision'(2000) confined the use of General Anaesthesia to the hospital setting. Since that time, the use of conscious sedation has increased as an alternative to general anaesthesia (see later).

The Poswillo report criticised the existing definitions of sedation on the grounds that they failed to emphasise the essential basic element of hypnotic suggestion and reassurance and emphasised central nervous system

depression rather than mood alteration. It made the principle recommendation that:

Simple dental sedation be defined as "A carefully controlled technique in which a single intravenous drug or a combination of oxygen and nitrous oxide, is used **to reinforce hypnotic suggestion and reassurance** in a way which allows dental treatment to be performed with minimal physiological and psychological stress, but which allows verbal contact with the patient to be maintained at all times, The technique must carry a margin of safety wide enough to render unintended loss of consciousness unlikely."

(Poswillo, 1990) (p.6) (emphasis added)

Later definitions, however, for example the report by the Standing Dental Advisory Committee of the Department of Health (2003) revert to the older formulations:

"A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely." p.15

This literature review will review papers relating to: the prevalence of dental anxiety and its treatment, the effectiveness of inhalation sedation techniques, the uses of hypnosis in dentistry and the evidence for the use of the two techniques in combination. It will critically analyse the existing research base on hypnosis and Inhalation Sedation in Dentistry and identify the next steps necessary to extend the knowledge base.

## **Dental Anxiety**

The effects of dental anxiety for patients may be far reaching, not only in terms of poorer oral health, but on their functioning in their daily lives. A qualitative study identified physiological, cognitive and behavioural impacts, together with impacts on health (sleep and oral health) and social impacts (work, relationships, taboo and leisure) (Cohen et al., 2000).

### **Prevalence**

Dental anxiety is ubiquitous throughout the developed world, and does not seem to be reducing. It is measured in different ways, but commonly the Dental Anxiety Scale (DAS) (Corah et al., 1978b) or the Modified Dental Anxiety Scale (MDAS) (Humphris et al., 1995, Humphris et al., 2000). The former scale has possible scores ranging from 4-20, and the authors recommend that scores of 13-14 should alert the operator to dental anxiety and that a score of 15 or over reveals a highly anxious individual (Corah et al., 1978b). The MDAS was developed to address the fact that the DAS has no question relating to fear of injections, which has been identified as a stimulus that provokes high anxiety (Gale, 1972, Wardle, 1982). It has possible scores of 5-25 with a score of 19 or over probably indicating dental phobia (Humphris et al., 1995). This scale has been extensively investigated and has demonstrated reliability (internal consistency and time stability), validity and UK norms are available (Humphris et al., 1995). Many other scales have also been used although research indicates that there is limited agreement between them (Locker et al., 1996)

The previous Adult Dental Health Survey in 1998 reported that 64% of dentate adults are somewhat or definitely nervous of dental treatment and 49% of visiting the dentist (Walker and Cooper, 2000). There was more anxiety reported by those who report only going to the dentist when they have trouble with their teeth, 46% definitely agreeing with the statement 'I always feel anxious about going to the dentist' compared to 32% of the population as a whole (Nuttall et al., 2001). The most recent survey in 2009 (NHS, 2011) used the MDAS for the first time and found that 12% of respondents scored in the extreme dental anxiety range with a further 36% being slightly to fairly anxious. Anxiety was demonstrated to be a barrier to receiving regular dental treatment (Hill et al., 2013).

Data on the prevalence of dental anxiety is available from many countries see table 1.

Lautch (1971) in his classic paper on dental phobia states: "a fear of dental treatment is, indeed so common that it can almost be considered normal unless of such a degree as to interfere with much needed dental care" p151, but a recent review of studies in the USA concludes that dental anxiety levels remain stable against a backdrop of increasing general anxiety in the US (Smith and Heaton, 2003).

Country/City	population	measurement	%anxious	%phobic	reference
Sri Lanka	First visit patients to dental hospital n=503	DAS	32	12	(Ekanayake and Dharmawardena, 2003)
Stockholm	Randomly selected residents postal survey n=704	Questionnaire based on DSM1V definition of phobia	Not reported	Injections 1.6 Dentists 2.1	(Fredrikson et al., 1996)
Belfast, Helsinki, Jyvaskyla Dubai	Dental hospital admissions clinics n=800	MDAS	Not reported	Belfast 19.5 Helsinki 6 Jyvaskyla 8.8 Dubai 3	(Humphris et al., 2000)
Toronto	Randomly selected residents postal survey n=3055	DAS Gatchel Fear Scale (fear of dental treatment on a scale of 0-10 Single item categorical scale	16.4	Not reported	(Locker et al., 1999)
New Zealand	18 year olds part of birth cohort study n=805	DAS	8	4.5	(Locker et al., 2001a)
UK	Random sample of UK addresses, face to face interviews with adult n=1800	DAS	Not reported	11	(McGrath and Bedi, 2004)
North West UK	3workplaces n=255	DAS	20	13.3	(Mellor, 1992)
Denmark	Random adult sample telephone interview n=565	DAS	6.0	4.2	(Moore et al., 1993)
Iceland	Postal questionnaire to previous child sample 22 years on n=1192	Questionnaire based on DSM1V and single question on avoidance due to fear	6.3	1.8	(Ragnarsson et al., 2003)
The Netherlands	Children age4- 11 attending general practice n=2144	Dental subscale of the Children's Fear Survey	8	6	(ten Berge et al., 2002)
Australia	Random sub- sample of adults, postal questionnaire n=?	DAS	14.9	Not reported	(Thomson et al., 1996)
North Jutland Denmark	All children aged 6-8 enrolled in municipal dental health service n=1493	Children's Fear Survey Schedule Dental subscale	7	Not reported	(Wogelius et al., 2003)
Montana USA	1 <sup>st</sup> 100 consecutive new patients at student health service	DAS Dental anxiety questionnaire	Not reported	5	(Woodmansey, 2005)

## Table 1 Prevalence of dental anxiety internationally

In many studies, women or girls reported higher levels of dental anxiety than men or boys (Kleinknecht et al., 1973, Mellor, 1992, Moore et al., 1993, Smyth, 1993, Locker et al., 2001a, ten Berge et al., 2002, Ekanayake and Dharmawardena, 2003, Ragnarsson et al., 2003, Wogelius et al., 2003, , Schuller et al., 2003, NHS, 2011). This could, however, be related to societal gender roles, women being more likely to admit to fears and anxieties than men, although one study suggests that this is not the case, rather that women may be more susceptible to social transmission of fears and phobias than men (Fredrikson et al 1996).

Income levels and educational achievement have been correlated with dental anxiety levels, individuals with high income levels reporting less anxiety and low educational achievement being associated with more anxiety (Moore et al., 1993, NHS, 2011).

High levels of dental anxiety have been associated with poorer oral health (Hakeberg et al., 1993) and oral health quality of life, including having fewer remaining teeth (Ragnarsson et al., 2003). One study found no difference in DMFT (decayed, missing or filled teeth), but the contribution of these elements differed between the high and low fear participants. High fear individuals had a significantly higher number of decayed and missing teeth and a lower number of filled teeth than low fear individuals, possibly reflecting the differences in attendance patterns (Schuller et al., 2003). The 2009 Adult Dental Health Survey found that patients with more restorations had lower levels of anxiety (Hill et al., 2013).

However, the reasons for this remain in doubt. It could be that dental anxiety prevents the patient seeking treatment and they therefore experience symptoms of oral neglect such as pain (McGrath and Bedi, 2004). On the other hand, poor dental health may contribute to dental anxiety, or there may be a reciprocal relationship.

There is no doubt that high levels of dental anxiety are a barrier to dental attendance (Schuller et al., 2003), and that avoidance behaviour is a characteristic of dental phobia. A recent telephone survey found that 24% of people cited anxiety as a reason for not attending the dentist regularly (Goodwin & Pretty 2011). Even amongst attending patients, a recent study using the Indicator of Sedation Need (IOSN) demonstrated that 5.3% of patients assessed were likely to need treatment under sedation (Pretty et al 2011). People with DAS and MDAS scores indicating dental phobia, may, nevertheless attend the dentist, albeit less frequently or only when in pain (Schuller et al., 2003). The studies using questionnaires based on the DSM - 1V definitions of phobias (Fredrikson et al., 1996, Ragnarsson et al., 2003), seem to show lower percentages of dental phobia than those based on specific dental scales. The question arises as to whether these different scales are measuring the same constructs.

### Aetiology

#### Conditioning

Dental phobia has been considered as a simple phobia (Fredrikson et al., 1996), but it is recognised that dentally anxious individuals do not represent a homogenous group and many factors affecting it have been identified. The conditioning effect of a bad dental experience is one of the most important. Ragnarsson et al (2003) found that more phobic people than anxious ones attributed their fear to an adverse incident (90.5% vs. 65.8%), although the

number of phobics in this sample was small (n=21). In another study, more than half of the people surveyed reported one or more bad experiences, mainly in childhood, and this was associated with higher scores on the DAS (Woolgrove and Cumberbatch, 1986). Dentally phobic individuals studied by Lautch (1971) all reported a bad dental experience on their first dental visit, but a second bad experience was necessary in the majority before phobia developed.

Some of these studies could be criticised because they are based on memory, rather than on longitudinal data. Attempts have been made to address this criticism by carrying out longitudinal surveys of large populations e.g. the Dunedin Multi-disciplinary Health and Development Study in New Zealand (Silva and Stanton, 1996). Individuals in this study showed varying dental anxiety during the study period and the authors argue that there seems to be no evidence that conditioning factors played a part in the onset of dental anxiety in adulthood (between 18 and 26 years of age) even though it may have done so between 15 and 18 years (Thomson et al., 2000).

Other evidence for the conditioning of dental fear shows that a process of latent inhibition may protect some individuals from acquiring fear and a significantly worse dental experience is necessary to produce anxiety (Davey, 1989, de Jong et al., 1995). Latent inhibition is a reduction in conditioning that occurs when an unconditioned stimulus is presented a number of times before it is paired with the conditioning stimulus. In dental anxiety, this has been shown to relate to several relatively pleasant dental

visits before the patient has a bad experience. This may also operate in children (Townend et al., 2000).

In children, conditioning may be only one of a number of factors implicated in the development of dental anxiety, though reports of traumatic experiences were significantly more frequent in anxious than non-anxious children in one study (Townend et al., 2000).

Dental anxiety is sometimes present in children even before any treatment experience. One study showed almost equal prevalence of dental anxiety between 6-8 year-olds who had and had not experienced dental treatment (5.2% and 5.5% respectively) (Wogelius et al., 2003). In addition, children in another study (Arnrup et al., 2003) rarely reported negative dental experiences as a cause of behavioural problems, but negative experiences of the relationship between the child and dental personnel were common (52% of children).

### **Cognitive factors**

Anxious patients typically expect to have negative experiences when they visit the dentist and this expectation is thought to keep their anxiety high. The thoughts of anxious patients play a role in maintaining their dental anxiety, with highly anxious patients reporting negative or catastrophising self-verbalisations in one small study (de Jong and ter Horst, 1993). A larger population based study reported more negative thoughts about dentistry amongst dentally anxious people (Locker et al., 1997). These types of thoughts distinguish anxious from non-anxious patients (de Jong et al., 1995). A questionnaire has been developed based on these findings – the Dental Cognitions Questionnaire (de Jong et al., 1995) which accurately

distinguishes anxious from non-anxious patients and provides support for the theory that cognitions about the dental situation, and about the person's ability to cope, are important in the fear response (Beck et al., 1985, Beck, 1976).

Dentally anxious individuals report having less control over their anxious thoughts (Kent, 1985a, Kent, 1989a, Locker et al., 1997).

Imagery is also important, with dental phobic volunteers showing marked physiological reactions to images of dentistry and rating the scenes as highly aversive (McNeil et al., 1993).

Anxious mood affects the memory for previous dental experiences, so they are recalled as more unpleasant than when anxiety is high (Kent, 1989b). Memory has been shown to be important in the maintenance and development of anxiety. Patients with dental fear may remember negative experiences more vividly (Hall and Edmondson, 1983) and may even restructure their memories of dental experiences as more painful and unpleasant than they actually were (Kent, 1985b). However, significantly more pleasant experiences than expected can result in the reduction of anxiety levels (Kent and Warren, 1985) providing that the comfortable experience is perceived as typical (Kent, 1986b). These findings mirror the anxiety literature as a whole.

Embarrassment has been shown to be important to avoidant phobic patients in a Danish study with feelings of embarrassment about dental neglect being related to social powerlessness when relating to dentists (Moore et al., 2004).

A large sample of Australian dental patients found that cognitive aspects such as perceptions of uncontrollability, unpredictability, dangerousness and disgustingness were more likely to be associated with dental anxiety than negative experiences including pain, although 70% of those with high dental fear had experienced pain (Armfield, 2010).

Cognitive aspects of anxiety have been shown to affect pain thresholds and tolerances, with experimental electrical pulp stimulation producing lower pain tolerance and pain threshold levels when administered in a dental surgery than in a laboratory context. The participants in this experiment also failed to discriminate between when they first felt a sensation and when they first felt pain in the dental setting, whilst they made a clearer distinction in the laboratory. The authors suggest that this may be important as dental patients may not be able to distinguish between non-painful and painful sensation in dentistry (Dworkin and Chen, 1982).

In contrast, dental anxiety has been shown to be related to inaccurate and increased predictions of pain rather than increased pain perception in reality. In highly anxious patients several experiences of the lower actual pain experiences are needed before an effect is seen on the original predictions and the predictions revert to the inaccurate overestimates quickly when experiences cease for a time. This relationship was also shown for predicted and actual anxiety during treatment (Arntz et al., 1990). The patients in this study only attended for two treatment visits, so it is possible that more disconfirmations of predicted pain and anxiety may have a more long term effect.

#### **Specific treatment factors**

Anxious patients are likely to find dental treatment unpleasant (Smyth, 1993). When patients are asked what frightens them about the dental situation, both anxious and non-anxious patients rank their fears similarly with fear of extractions, drilling, injections and negative attitudes on the part of the dentist all coming high up in the list (Gale, 1972). In other studies drilling was still important, but overtaken by the sight and sensations of the local anaesthetic (Kleinknecht et al., 1973). Pain perception is related to fear of pain and some dental phobic patients seem to have a lowered pain threshold (Lautch, 1971) although it is not clear whether the bad experiences led to the anxiety, or whether the anxiety was affecting the pain perception. In contrast, another study found that, whilst expectation of pain was prevalent in anxious compared to non-anxious patients, the anxious patients actually experienced much less pain than they expected during operative procedures (Kent, 1984).

Anticipation of pain has been shown to be related to anxiety in both hospital and general practice patients, and specific treatments (extractions, local anaesthesia) which were expected to be more painful were associated with more anxiety (Wardle, 1982). Fear of pain is prevalent in dental phobics (Hall and Edmondson, 1983) and this study found that the recall of the phobic patients for negative experiences was very vivid, particularly remembering the negative verbalisations the dentist offered at the time (Hall and Edmondson, 1983).

In addition, pain during treatment has been associated with previous painful treatment, dental anxiety, expectation of pain and feelings of lack of control (Maggirias and Locker, 2002).

A group of fears known as blood-injury fears have been suggested to be related to dental fear and anxiety, but there seems to be little overlap between the two (Locker et al., 1997). Where they do co-exist, there may be other anxiety problems in these individuals.

#### **Effects of the Dentist – Patient Relationship**

The attitude of dentists may be important in the aetiology and maintenance of dental anxiety and phobia, although good quality research is lacking (ter Horst and De Wit, 1993). These authors were unable to draw any firm conclusions from available research on this topic 1987-1992. In one survey, people who were dentally anxious were 5 to 10 times more likely to have had negative experiences of dentists' behaviours (Moore et al., 1993). A slightly different concept is that of satisfaction with dental care. Here dentists' behaviours seem to be very important. In one large survey of young people 15% expressed dissatisfaction with their dental care and this was related to their beliefs about the dentist, past painful experiences and dental anxiety (Skaret et al., 2005). Recent qualitative research using focus groups emphasises dentists' attitudes and behaviours. It appears that, if anxiety is responded to sympathetically the patient may not blame the dentist for bad experiences. Patients were aware of a gap between their ideas of acceptable behaviour and dentists' perceptions, particularly in communication skills (Newsome and Wright, 2000). This is echoed in an American study of treatment decision-making involving non-anxious

patients. (Redford and Gift, 1997) Dentists focused on the mouth and described patients in terms of dental conditions and patients seemed aware of this.

Consultations with anxious and phobic patients in a specialist centre (Kulich et al., 2000) revealed that similar factors were important. These studies reinforce similar studies of doctor/patient encounters and relationships, concentrating on their 'non rational' and emotion laden aspects (Barry et al., 2001).

In children, non-anxious individuals rated their dentist as more empathic than anxious children, although all the children in this study rated their dentist as fairly sensitive to their needs (Townend et al., 2000).

#### Familial and cultural influences

There is little information about how culture affects dental anxiety, although a recent review suggests that it may be important, at least in children (Folayan et al., 2004).

The influence of family experience and dental attitudes has been a matter of debate, some asserting it to be highly important (Shoben and Borland, 1954, Freeman, 1985) and others disputing this (Forgione and Clark, 1974). One study showed a relationship between the child's dental anxiety and the mother's state anxiety at the child's dental visit, but not between the child's dental anxiety and the mother's reported dental anxiety (Townend et al., 2000). However, it could be argued that the child's anxiety was contributing to the mother's anxiety at the visit, rather than the other way around. One study showed that more young people expected dentistry to be traumatic because of stories told by friends and family, or in the media, than

because of bad experiences (Kleinknecht et al., 1973). However, the sample was not selected for its dental anxiety, but was a college and high school student sample. In one sample of children with behavioural problems, levels of parental emotional stress during dental visits, parents' own dental fear and the parents' locus of control was found to be related in some subgroups of fearful children (Arnrup et al., 2003).

Attachment style (Barnes, 1995) has been proposed to be a contributing factor in the modulation of dental anxiety (Eli et al., 2004b). Attachment style is a pattern of interaction between young children and their primary care giver, which is proposed to influence inter-personal relationships in the longer term. Three main types have been identified; secure, avoidant and ambivalent. A secure attachment style indicates confidence of the child in their caregiver and they are able to use them as a base from which to explore new experiences, children with avoidant or ambivalent styles are less able to do this. In a study based on Kibbutzim (Eli et al., 2004b), although the best predictor of present dental anxiety was recalled anxiety from the past, a secure attachment style was somewhat associated with a reduction in dental anxiety and a more positive evaluation of the present dentist. However, an avoidant style also predicted reduction in dental anxiety so the significance of the attachment style is unclear. Further work would be needed to clarify whether attachment style is implicated in dental anxiety.

#### **Other factors**

Personality factors have been shown to associated with dental phobia in some studies. For example, higher neuroticism measured by the Eysenck Personality Inventory was shown by samples of phobic patients compared

with matched non-anxious control groups (Lautch, 1971, Hall and Edmondson, 1983). In a one study, initial apparent correlations between neuroticism and others of the 'big 5' personality dimensions disappeared once initial levels of anxiety were controlled for (Vassend et al., 2000). In children, a distinction has been made between dental anxiety/fear and behavioural and management problems, and subgroups of fear and personality variables (e.g. fearful extravert outgoing, fearful inhibited and externalising impulsive) identified (Arnrup et al., 2003) that appear to affect treatment outcome.

High levels of dental anxiety in young adults (DAS scores of 15 or over) may be associated with higher levels of other psychological disorders such as conduct disorder, agoraphobia, social phobia, simple phobias or alcohol dependence than non-dentally anxious individuals (Locker et al., 2001a). These individuals were also more likely to be still dentally anxious at age 26, whereas those without other psychological problems were more likely to have overcome their anxiety. However, dentally anxious individuals with psychological co-morbidity were still a minority amongst this population, so other factors are probably more important and it is not possible to determine a causal relationship between the two (Locker et al., 2001a). This was confirmed in a follow-up study of the same population showing a role for both psychological problems and conditioning effects in the development of dental anxiety (Locker et al., 2001b).

Self-efficacy and locus of control are two psychological constructs that have been related to dentistry (Kent et al., 1984, Kent, 1987, Skaret et al., 2003). Locus of control has two dimensions, internal – those who believe

themselves in control of what happens to their lives and external – those who believe that their lives are controlled by external factors. Self-efficacy relates to a person's perceived ability to cope, either generally or in specific situations and may be related to self-esteem.

Anxious patients show less self-efficacious control in the dental situation (Kent, 1987), but general self-efficacy seems to be only weakly correlated to dental anxiety (Skaret et al., 2003).

People with good oral health may be more likely to have an internal locus of control than those with poor oral health (Kent et al., 1984). Locus of control has also been related to the desire for and the reaction to, preparatory information before surgical and other procedures (Auerbach et al., 1976). An internal locus of control may be related to an increased desire for and a more positive reaction to preparatory information, whereas those with an external locus of control may be made more anxious by such information.

### A multi-factorial Aetiology

It can be seen from the above that dental anxiety/phobia is not a simple unitary concept. Its aetiology can be seen to be truly multi-factorial and variable between dental patients. Because of this a system of classifying dentally anxious individuals has been proposed – The Seattle System. This breaks down dental fear into four categories: Simple conditioned fear of specific dental stimuli; anxiety about somatic reactions during dental treatment; associated with generalised anxiety states; and multiphobic symptoms and distrust of dental personnel (Locker et al., 1999). These diagnostic categories seem to be reasonably distinct and may be useful in planning treatment for dental anxiety with the most common type I fear of specific dental stimuli being simplest to treat using desensitisation and relaxation strategies (Locker et al., 1999).

In children, recent research has also looked at sub-groups of children and attempted to draw conclusions about the nature of their anxiety, complicated by the observation that failure to comply with dental treatment may not always be related to fear and anxiety in children (Arnrup et al., 2003).

#### Treatment Methods for Dental anxiety

#### Behavioural treatment methods for dental anxiety

Dental anxiety causes problems for patients and dentists who provide their care. In children, it seems that the higher the anxiety levels, the more likely they are to present management problems when they attend the dentist (Wogelius et al., 2003).

In 1986 the journal Anesthesia Progress published the proceedings of a research workshop on dental anxiety. The papers contained within the journal addressed the need for research into methods of anxiety control for adults and children relating to both behavioural and pharmacological methods (Dworkin, 1986, Houpt, 1986, Jastak, 1986, Milgrom, 1986, Ridley-Johnson and Melamed, 1986). Milgrom (1986) concludes that "Clinicians tend to use the kitchen sink approach in treating patients. That is, use enough different approaches to insure success. Unfortunately, much of our research has an element of the same strategy." (p.8) A more recent review (de Jongh et al., 2005) draws similar conclusions, pointing out that many existing randomised controlled trials include treatment packages consisting of multiple strategies so it is difficult to draw

conclusions about the effects of different aspects of the treatments. A second conclusion is that dental anxiety is a very general term that may cover a heterogeneous group of patients, and that different types of dental fear may need different interventions, so the research question posed should not be 'what works for most people?', but 'what works for whom?' (de Jongh et al., 2005). This could be true for both adults and children (Arnrup et al., 2003). A recent review suggests that patients with low, moderate and high levels of dental anxiety should be offered different interventions which are proportionate to their anxiety levels, with high anxiety patients with urgent treatment needs being offered pharmacological interventions such as conscious sedation or general anaesthesia (Newton et al., 2012).

Meta-analysis of behavioural interventions has also proved difficult (Kvale et al., 2004) with significant heterogeneity amongst interventions and the design aspects of studies (e.g. sampling, populations studied, outcome measures etc.) making analysis difficult and few studies meeting the basic criteria for randomized controlled trials. Nevertheless, effect sizes in 33 studies showed reductions in self-reported anxiety, 2 studies no change, but 8 studies indicated slight negative changes. The review also attempted to calculate effect sizes for post-treatment dental attendance, but only 13 studies could be classified as controlled and it was not possible to calculate a single effect size because of the heterogeneity but the authors suggest that behavioural treatments may give long term results.

Many studies suffer from poor response rates and high dropout rates, further compromising the ability to draw firm conclusions (Moore et al., 2002, Aartman et al., 2000). In addition to these problems, it has been considered

that self-report measures are insufficient and physiological responses such as heart rate (HR), skin conductance response (SCR) and Electromyograms (EMG) should be related to self-report variables (Harrison et al., 1985). Unfortunately, physiological measures are difficult during periods of patient movement and activity, and, even amongst 11 patients in one study each patient's physiological responses were different (Harrison et al., 1985). A Cochrane protocol on psychotherapy for dental anxiety was published

with two objectives:

 To assess the effectiveness of using psychotherapy versus placebo control for the treatment of dental anxiety in patients undergoing dental procedures.
 To determine which psychotherapy approach is most effective in reducing anxiety. (McGoldrick et al., 2001a)

Unfortunately, this protocol was later withdrawn and the review not published.

# Treatment methods based on the cognitive aspects of dental anxiety

Treatment methods based on the cognitive aspects of dental anxiety have been recommended for example cognitive restructuring, reattribution, information provision, stress inoculation training and enhancing of control over the situation and anxious cognitions (Kent, 1989a). One study has measured the change in mood over a course of psychological treatment (a cognitive based treatment and a relaxation based treatment) using a Mood Adjective Checklist (MACL) showing an improvement in feeling pleasant and feeling relaxed in a dental situation. These measurements were taken when imagining being in a dental situation, not actually there (Hakeberg et al., 1997). There was no difference found between the two types of treatment.

Perceived control has been investigated, but the results have been mixed, and the use of a signalling device may increase anxiety in certain situations and may be related to locus of control (Corah, 1973, Corah et al., 1978a). When compared to relaxation tapes and active distraction perceived control appeared to have no effects for either high anxiety or low anxiety individuals (Corah et al., 1979b).

Self-efficacy is a psychological construct that relates to people's confidence that they will be able to produce a good outcome by their behaviour. It has been proposed that if patients are more confident in their ability to cope then they may actually cope better in the dental surgery situation (Litt et al., 1993). This was supported by a study which compared standard preparation, oral pre-medication, relaxation training and relaxation training combined with false biofeedback to convince patients that they were highly skilled at relaxing. The addition of the enhancement of the patients' belief that they could relax was related to less peri-operative distress during an oral surgery procedure (Litt et al., 1993). In addition, relaxation training was found to be superior to oral pre-medication. This study attempted to control for expectancy and placebo effects by asking patients if they found the interventions credible as a way of enhancing coping with the surgery and found no differences in credibility ratings. However, it could be argued that the false biofeedback condition was specifically aimed to increase expectancy of coping skills rather than directly influencing a personality trait of self-efficacy.

Treatment methods based on methods developed for panic disorder have been adapted to treat dental anxiety, including elements such as; Socratic questioning to deal with patient's misinterpretations of bodily sensations and imagery, their replacement by realistic interpretations and restructuring images (Vassend et al., 2000). In the short term, this produced significant decline in dental anxiety comparable to applied relaxation and the use of nitrous oxide.

One study compared Cognitive Behavioural Therapy (CBT) based on Stress Inoculation Training with a behavioural treatment (BT) involving relaxation training and desensitisation towards filmed dental treatment and treatment by a dentist skilled in dealing with anxious patients. Both CBT and BT reduced anxiety, but CBT was not more effective than BT (Getka and Glass, 1992).

A recent critical review of approaches to treatment for dental anxiety in adults (Gordon et al., 2013) included twenty two randomised controlled trials (RCTs) the majority of which involved Cognitive Behavioural Therapy (CBT) of varying types. The authors conclude that there is sufficient evidence that CBT interventions effectively reduce dental anxiety and avoidance, but criticise many of the studies for methodological issues including differing criteria for inclusion of patients, small sample sizes and definitions of treatment success. They also suggest that the results of a metaanalysis of behavioural interventions (Kvale et al., 2004) should be treated with caution due to its age and criticism of the calculation of effect sizes based on combining controlled and uncontrolled trials, a limitation recognised by the authors of the meta-analysis. Nevertheless, CBT seems to

be the most promising therapeutic intervention to date and is recommended for highly anxious patients (Newton et al., 2012).

#### **Provision of information**

Provision of information should include information about the sensations that are likely to be experienced as it has been shown that patients consistently overestimate the unpleasantness of these (Lindsay et al., 1984), however, care should be taken to avoid warning the patient that experiences will be painful or unpleasant, as this has been shown to increase anxiety and pain perception, (Lang et al., 2005).

Small but significant reductions in anxiety can be produced by the provision of appropriate information about pain control and stop signals (Jackson and Lindsay, 1995), but this may be modified by individual's locus of control, people with an internal locus of control showing better adjustment to surgery following specific information, whilst externals preferred general information only (Auerbach et al., 1976).

In a study of different types of information given to patients scheduled for dentoalveolar surgery (Ng et al., 2004) basic information was compared to basic information plus details of operative procedures , basic information plus details of expected recovery and basic information plus details of operative procedures and expected recovery. Measures of self-reported dental anxiety on a 0-100 scale were taken during treatment. The results showed that there was a difference between high and low trait anxiety patients, with information about expected recovery being effective for both but procedural information only lowering anxiety for low anxiety patients.

Information may also modulate the experience of pain, a study on periodontal probing (van Wijk et al., 2004) provided an experimental group of periodontal patients with written information on stop signals and cognitive and behavioural coping strategies with the control group given standard information about periodontal disease. The study confirmed that patients consistently overestimate pain experience regardless of the information provided, but the experimental group showed a small difference on the evaluative scale of the McGill Pain Questionnaire (Melzack, 1975). The authors admit that this effect was small and speculate that patients may not have read or understood the information brochure and suggest that future studies have a more complex approach including providing the information more than once and practice in coping strategies (Van Wijk et al, 2004).

The effects of information on pain and anxiety deserve further study and with future larger studies may show more robust results.

#### Systematic desensitisation or exposure therapy

Systematic desensitisation is a procedure which makes use of the idea that it is impossible to be relaxed and anxious at the same time (Wolpe, 1958). The patient is taught muscular relaxation and then encouraged to experience the feared object or situation in a graded, controlled manner, from the least feared to the most feared aspect, only moving on when the particular item in the 'hierarchy' can be experienced whilst relaxed (Levin and Gross, 1985, Gale and Ayer, 1969). This has been used in various ways and compared to other treatments for dental anxiety (Moore et al., 2002). The exposure to the feared stimulus can be in imagination, on video or direct and live. The study by Moore et al (2002) indicates a possible advantage in long term follow-up for video exposure. Some believe that the content of the imagery generated and the control of the patient over their imagery influences the success of behavioural therapy for dental fear (Eli et al., 2004a). These authors investigated differences between those patients who succeeded or failed in tolerating dental treatment following a behaviour management programme which included relaxation training, positive imagery and gradual exposure to a fear hierarchy. One main trait which seemed to predict success was the 'Poor Attention Control' scale of the Short Imaginal Processes Inventory (SIPI) which measures distractibility and mind wandering. The risk of therapy failure increased about 11 times for each level of increase in the scale, compared to 3 times for one point increase on the DAS. However, the study was small (22 successful patients vs. 18 unsuccessful) and the SIPI measured retrospective to the treatment and the success or failure. It has been argued that relaxation training is not necessary for success, and that graded exposure alone may be successful. The majority of highly anxious patients dental patients may be successfully treated using gradual exposure and tell show do methods (Aartman et al., 1999) and the anxiety reduction obtained is maintained in the medium term (Aartman et al., 2000).

#### Flooding

Flooding is a procedure characterised by the participation of the phobic patient in their feared situation without the possibility of escape or avoidance. It is argued that this will be effective in reducing anxiety as the initial high levels are not maintained and the reduction in anxiety then retrains the patient to be able to cope in future. The procedure can be carried

out in reality or in imagination. The procedure carried out in imagination seems to be more effective if realistic (rather than worst case) situations are imagined (Mathews and Rezin, 1977).

# Comparisons between pharmacological and behavioural treatments

Dental practitioners report seeking training in and using a variety of techniques to manage anxious patients including 'patient management', hypnosis, oral, intravenous and inhalation sedation (Edmunds and Rosen, 1989). However, there is a weak evidence base to help practitioners to decide which technique to choose for which patient.

Some (de Jongh et al., 2005, Aartman et al., 1999) argue that pharmacological methods (conscious sedation and general anaesthesia) should be reserved for situations where the amount or type of treatment need would further traumatise a patient as these methods do not treat the dental anxiety. The treatment plan in these situations would allow for the bulk of the treatment and any urgent treatment to be carried out using pharmacological means, after which behavioural methods could be used to address the dental anxiety and enable simple treatment to be accepted by the anxious patient. Since behavioural methods seem to produce long term results (Aartman et al., 2000, Moore et al., 2002), the patient would seek ongoing dental care (de Jongh et al., 2005). This is also considered true in the case of children (Arnrup et al., 2003).

When behavioural treatments have been compared to general anaesthesia, both produce a reduction in dental anxiety but more of the patients treated

behaviourally were able to successfully complete dental treatment (78% vs. 53% of the GA patients (Berggren and Linde, 1984)), or continued treatment following the behavioural treatment or IV sedation (70% in the psychological treatment group vs. 20% in the benzodiazepine group (Thom et al., 2000).

It may be that dentists decide on the treatment modality appropriate for a patient based on judgements of how much treatment is required, rather than on the extent of their anxiety (Aartman et al., 1999), which may be a difficulty as behavioural management seems to produce more anxiety reduction when compared to intravenous sedation, and further, that more patients maintain high levels of dental anxiety following IV sedation (Aartman et al., 2000). In addition, it appears that general dental practitioners almost always request pharmacological treatments (mainly IV sedation) rather than behavioural treatments when they refer their anxious patients for specialist care (McGoldrick et al., 2001b). In practice, many of these patients could be treated using behavioural methods and patients, given the choice, do opt for behavioural methods when suggested by dentists in specialist settings (Aartman et al., 1999, McGoldrick et al., 2001b).

Recently, there have been attempts to design tools to help practitioners decide when conscious sedation is appropriate for an individual patient taking into account their anxiety levels, treatment needs and fitness levels/medical conditions but this is not yet in general use (Coulthard et al., 2011). A simple way of deciding which treatment is chosen has been

suggested, based on the anxiety level and treatment urgency (Newton et al., 2012).

## **Inhalation Sedation**

Inhalation sedation using mixtures of nitrous oxide and oxygen are widely used not only in dentistry but also in other areas of medicine where pain and anxiety control are needed such as childbirth. Obstetric settings generally use a single cylinder containing a mixture of 50% nitrous oxide and 50% oxygen (Entonox), whilst in dentistry separate supplies are provided and the concentration of nitrous oxide is carefully titrated to the needs of the individual patient. In some studies fixed concentrations have been used, commonly 25% nitrous oxide 75% oxygen (Cooper et al., 1978, Edmunds and Rosen, 1977), although 50/50 premixed gases have been reported (Collado et al., 2006).

#### Mechanism of Action

Sub- anaesthetic concentrations of nitrous oxide produce effects on the individual which reduce the effectiveness of cognition, learning and memory. New brain imaging techniques (such as positron emission tomography PET) measure changes in brain activity in vivo and have been used to investigate the actions of nitrous oxide at the level of neuronal activation. Low concentrations of nitrous oxide (20%) have been shown to activate certain brain areas (anterior cingulate cortex, areas 24 and 32) whilst reducing activation in others (posterior cingulate, hippocampus, parahippocampal and visual association cortices) (Gyulai et al., 1996). These areas may be associated with the impairments in psychomotor and

cognitive functioning during nitrous oxide inhalation. Depression of the hippocampus and parahippocampal areas may be related to memory impairment (Gyulai et al., 1996).

Electroencephalographic (EEG) recordings during nitrous oxide inhalation have been investigated and show some changes during nitrous oxide inhalation, although little actual sedation (Rampil et al., 1998). In other studies a reduction in general arousal levels was demonstrated which could account for the slowing of performance in complex tasks (Fowler et al., 1988, Pang and Fowler, 1997).

One well established effect of sub-anaesthetic concentrations of nitrous oxide is analgesia and in some clinical applications this is its main function. Positron emission tomography in humans exposed to noxious stimuli with nitrous oxide at 20% show changes in brain activation with the abolition of pain responses in the thalamus, anterior cingulate and supplementary motor area and activation of areas of the infralimbic and orbitofrontal cortices (Gyulai, 2004).

In the absence of painful stimuli, areas of the anterior cingulate (24 and 32) are activated during nitrous oxide inhalation (Gyulai et al., 1996) which parallels activation of these areas during opioid pain relief. This may suggest a similar mechanism for nitrous oxide pain relief since nitrous oxide aids the release of opioid peptides, at least in rats (Quock et al., 1985). These peptides, released in the peri-aqueductal grey area of the midbrain, stimulate descending noradrenergic neuronal pathways, releasing norepinephrine. This acts at  $\alpha$ 2 adrenoceptors in the dorsal horn of the spinal cord (Maze and Fujinaga, 2000). However, several studies have

assessed the effects of the opioid antagonist naloxone on nitrous oxide analgesia in humans, and produced conflicting results (Zacny et al., 1999). When this was tested on clinical pain (following wisdom tooth extraction) no effects were found suggesting that endogenous opioids may not contribute to nitrous oxide analgesia in clinical pain (Levine et al., 1982). To complicate matters further, it has been argued that the failure of naloxone to antagonise nitrous oxide analgesia is related to the rapid decline of naloxone levels in the brain whereas the actions of nitrous oxide are continuous over a much longer period (Gillman and Lichtigfeld, 1983). This problem can be overcome in experimental pain situations by presenting the pain stimulus at the time when brain levels of naloxone would be expected to be at their peak.

Attempts have been made to quantify the analgesic effects of nitrous oxide, on different types of pain and in both clinical and laboratory contexts. Low medium and high concentrations of nitrous oxide (20%, 30% and 40%) have been compared to 100% oxygen in cold pressor pain and showed a dose dependent reduction in pain intensity and 'bothersomeness'. Pain thresholds and tolerance to electrical pulp stimulation were both increased by nitrous oxide in both laboratory and clinical contexts (Dworkin et al., 1983a, Dworkin and Chen, 1982), but when real clinical procedures are used such as ultrasonic scaling (Bentsen et al., 2003) no such effects have been reported. Pain produced in clinical contexts is different to experimental pain, as experimental pain lacks any real meaning for the participant and they know that there will be no lasting effects. However, when pain is produced artificially, but given a clinical meaning, pain threshold and tolerance has been shown to reduce (Dworkin and Chen, 1982).

Tolerance effects (both acute and chronic) have been shown to affect the analgesic actions of nitrous oxide. Acute tolerance was demonstrated after breathing 38% nitrous oxide for 36-40 minutes and affected pain thresholds but not sensation threshold in one experiment, but for both in another (Ramsay et al., 2005). Chronic tolerance developed following multiple administrations of nitrous oxide for both pain and sensation thresholds which could not be explained by conditioning effects (Ramsay et al., 2005). The actions of nitrous oxide vary considerably both between people and within the same person at different times and the authors note that there was a large variation of response and only a small magnitude of acute tolerance developed.

Nitrous oxide inhalation sedation in the clinical setting has been shown not only to reduce anxiety, but also to enhance mood in both anxious and nonanxious dental patients (Zacny et al., 2002). Ratings of anxiety and unpleasant feelings were significantly reduced in the high anxiety patients and all patients regardless of their initial anxiety levels showed increases in positive mood states such as elation, having pleasant bodily feelings and feeling good.

### **Effectiveness**

A recent Cochrane review of sedation of anxious children in dentistry (Matharu and Ashley, 2006) included 61 studies where a drug or drugs were compared to a placebo or different drug or combination of drugs or where differing doses of the same drug were compared. The reviewers conclude

that the overall quality of the studies was poor and they were unable to reach any conclusions as to the preferred type of sedation for children. Nitrous oxide was tested in 8 studies as a sedative agent in its own right and was used in others as an adjunct to other methods. Where it was compared to placebo (Lindsay and Roberts, 1980, Nathan et al., 1988, Primosch et al., 1999, Veerkamp et al., 1993b) all studies reported improvements in behaviour or anxiety. When nitrous oxide was compared to intravenous and oral midazolam (Wilson et al., 2003, Wilson et al., 2002) no differences were found in treatment completion, but midazolam produced significantly deeper sedation, amnesia and required the patients to be longer in the sedation unit. In addition, in one study (Wilson et al., 2002) nitrous oxide provided more anxiety relief when it was used first in the crossover design. The authors speculate that this could be due to the amnesic effects of midazolam which prevented the patient from remembering the dental treatment. Nitrous oxide sedation has been shown to have long lasting effects on anxiety reduction (Veerkamp et al., 1993a, Veerkamp et al., 1995).

There is no corresponding review of sedation for adults in dentistry, but a Cochrane Review has been published which reviews the use of nitrous oxide for colonoscopy in comparison to other sedatives. A pre-mixed 50% N<sub>2</sub>O 50% Oxygen mixture was used in these studies, whereas, in dentistry it is more common to titrate the nitrous oxide according to the response of the patient. Also, the aim of the sedation was to control pain and discomfort rather than anxiety. Seven articles were included in the review and one showed that  $N_2O/O_2$  was better than sedation and four showed no difference

in the control of pain and discomfort whilst six showed the nitrous oxide groups recovered more quickly and patients in general were as satisfied or more satisfied with the procedure and less nausea was reported (Aboumarzouk et al., 2011).

De Jong et al (2005) argue that, although there is some scientific evidence for the effectiveness of inhalation sedation in reducing anxiety, other elements of the use of the technique including general anxiety reduction strategies, enhancing control and explanation and pain management might be more important than the pharmacological effects of nitrous oxide. Certainly, there is much in common between inhalation sedation and behavioural management methods of the treatment of dental anxiety (Aartman et al., 1999, Aartman et al., 2000).

In one study of children with behavioural management problems, 63% of the children needed behavioural techniques (tell show do, systematic desensitisation) to be integrated with inhalation sedation (Arnrup et al., 2003)

#### **Disadvantages**

A major disadvantage of the use of nitrous oxide in the dental surgery is the possibility of adverse or toxic effects. This is not a problem for patients who are receiving sedation for their dental treatment, but relates more to staff who are subject to chronic exposure in their working environment. Early studies involved operating theatre personnel and the effects of nitrous oxide were difficult to separate from the gas mixtures commonly used (Malamed, 1995). In response to these studies, a large scale study of American dentists and chair-side assistants was carried out in co-operation with the American

Dental Association (Cohen et al., 1980). This was a postal questionnaire with a study population of 22,555 dentists and 21,390 chair-side assistants. Within this, non-users of anaesthetic gases were compared to heavy and light users, most of who were exposed to N<sub>2</sub>O alone. Effects on the reproductive system were in line with earlier studies, female chair-side assistants showing 1.7 to 2.3 fold increase in spontaneous abortion following exposure to  $N_2O$  in the year prior to conception, the risk appearing to be dose dependent. Further, a 50% increase in spontaneous abortion was shown in the wives of heavily exposed male dentists. There was an increase rate of congenital abnormalities in the children of exposed chair-side assistants, particularly musculoskeletal abnormalities. In contrast to previous studies, this result was not shown by the wives of exposed male dentists. The authors suggest this may reflect the differences in anaesthetic practice, particularly the use of halogenated agents by anaesthetists, most of the dentists used N<sub>2</sub>O alone. Other studies showed effects on fertility, with women having high levels of exposure (above 5 hours/week) being only 41% as likely to conceive in each cycle as non-exposed women (Malamed, 1995). Significant increases in cancer of the cervix were shown amongst female chairside assistants heavily exposed to N<sub>2</sub>O; other findings on cancer were not significant. Increased incidence of liver disease was shown in line with previous studies. Kidney disease incidence was also increased, renal lithiasis in male dentists and urinary tract infections in female chair-side assistants. Finally, significant increases in general neurological disease were shown, particularly the symptom subset of tingling, numbress and muscle

weakness – dentists working with inhalational anaesthetics reporting 1.8 – 3.8 fold increase (Cohen et al., 1980).

This study, whilst alarming, has significant limitations. Any retrospective postal study has the possibility of responder bias, although the response rate here was high (70% approximately), the responses rely on the recall of individuals. In addition, no measures of actual exposure were available; high and low exposure rates being calculated on the number of hours of exposure. The responders were not asked about scavenging or other methods of reducing exposure. There were also differences in the populations of users and non-users of N<sub>2</sub>O, users being significantly younger and placing significantly more amalgam restorations than non-users (Cohen et al., 1980). One other confounding variable may be the habitual recreational abuse of N<sub>2</sub>O. This has been shown to be associated with peripheral neuropathy and up to 1-5% of dentists may abuse N<sub>2</sub>O (Yagiela, 1991).

Since this early study, concerns continued to be raised and the biochemical basis of  $N_2O$  toxicity became understood. Patients exposed to  $N_2O$  at 50% for 6-44 hours developed megaloblastic changes in bone marrow cells implicated  $N_2O$  in causing pernicious anaemia (Yagiela, 1991). The mechanism for toxicity is that  $N_2O$  affects the metabolism of vitamin B12, inactivating the enzyme methionine synthetase causing a variety of metabolic disturbances (Yagiela, 1991). Chronic  $N_2O$  exposure will affect cells which have a rapid turnover due to impaired DNA synthesis (Donaldson and Meechan, 1995). This mechanism has been proposed to account for the teratogenicity and haematotoxicity of  $N_2O$ , although recent

evidence indicates that teratogenicity involves more complex mechanisms

(Maze and Fujinaga, 2000).

Adverse Effects of Chronic Exposure to Nitrous Oxide		
<b>Reproductive Problems</b>	Reduced fertility	
-	Spontaneous abortion	
	Testicular changes*	
	Decreased sperm count*	
Neurological Defects		
Haematological and	Decreased leucocyte count	
Immunological Problems	Decreased leucocyte motility and chemotaxis	
	Megaloblastic anaemia	
Liver problems	1.7 (male), 1.6 (female) fold increase heavily exposed	
Kidney Problems	Rise in incidence of renal calculi (males)	
	Rise in incidence of genitor-urinary infection	
	(females)	
Malignancy	2.4.fold increase in cervical cancer in highly exposed dental surgery assistants	
Miscellaneous Cytotoxicity	Toxic effects on embryonic and tumour cells*	
*Animal Studies		
Adapted from Donaldson and Meechan (1995) p. 96		

#### Table 2 Adverse effects of chronic exposure to nitrous oxide

The older studies concerned workplaces where little attempt was made to

minimise exposure to N<sub>2</sub>O, and levels in the dental environment up to 7000 ppm have been reported without scavenging of the gas (Donaldson and Meechan, 1995). More recent studies of women operating room staff in Sweden and Finland could find no link between exposure to anaesthetic gases and spontaneous abortion or congenital malformation (Yagiela, 1991) and in California dental assistants working with N<sub>2</sub>O showed no increase in risk of spontaneous abortion providing that excess gas was scavenged (Rowland et al., 1995). In the UK the maximum acceptable occupational exposure over an 8 hour period is 100 ppm (Girdler and Hill, 1998). In the USA recommended levels of as little as 25 ppm have been proposed (Howard, 1997). As toxicity depends on length of exposure as well as concentration, the recommendations are based on a time weighted average.

Scavenging of gas is the obvious way to reduce exposure, and scavenging masks and active systems have been available for some time (Langa, 1968). Unfortunately, still not all dentists use them. A study in 2000 monitoring N<sub>2</sub>O levels in community clinics notes that no active scavenging and no increased ventilation was present. Monitoring of the air revealed a peak level of 700 ppm and a TWA exposure over 180 minutes of 277 ppm (Henderson and Matthews, 2000). An effective scavenging system is composed of a suitable nasal hood (either the scavenging hood or the Bain/Littell system) with the exhaling tube connected to a vacuum system (optimal vacuum flow rate 45 litres/minute) which vents the exhaled gases outside the surgery (Malamed, 1995). The double mask of the scavenging hood is more efficient than the Bain/Littell system as the latter depends on an airtight seal between the nasal hood and the patients face (Malamed, 1995) and a major source of pollution may be leakage from around the mask (Girdler and Hill, 1998). Adequate ventilation of the surgery is also important, not air conditioning as it circulates N<sub>2</sub>O into other parts of the building (Malamed, 1995).

However, effective, scavenging alone cannot provide complete protection for staff providing relative analgesia sedation. Other preventable sources of pollution include leakage from the equipment. Inhalational sedation equipment can operate for many years in the absence of maintenance but significant leakage of  $N_2O$  may occur and not be noticed in the absence of regular checks (Malamed, 1995).

Other major sources of  $N_2O$  pollution relate to the technique of the operator. A poor mask fit is an obvious cause of leakage, but even a well-fitting nasal

hood can leak, should the patient move about or move the mask. The behaviour of the patient also contributes to leakage, talking and mouthbreathing being significant (Girdler and Hill, 1998). In addition, disruptive behaviour by child patients and treatment of younger age groups have been shown to significantly increase N<sub>2</sub>O pollution (Donaldson and Meechan, 1995, Roberts, 1990).

The above illustrates the importance of the use of behavioural methods of patient management to reduce anxiety levels as far as possible before treatment to minimise the concentration of  $N_2O$  required for adequate sedation.

In the opinion of some consultant anaesthetists, sedation is more appropriate in a hospital than a dental surgery environment although they admit that it is impractical for all dental sedation to be provided by anaesthetists, dentists who provide even simple sedation such as IHS should receive appropriate training and follow guidelines for its use (Shearer et al., 2004).

# Hypnosis

### **Theoretical Overview**

#### **Historical overview**

Hypnosis has been extensively researched with the first scientific investigation being the Royal commissioner's investigation of Mesmer's animal magnetism in 1784 (Franklin et al., 2002). Mesmer believed that a 'magnetic fluid' flowed through all living things and that, initially by using magnets, later by channelling the fluid using his own body, baths of iron

filings, magnetised trees etc. people's health and functioning could be altered. Many of his patients underwent a 'crisis' during which they experienced convulsions or became insensible and after one or more sessions seemed cured of their problem. The commissioners conducted some quite sophisticated trials, including deceiving patients as to which tree was 'magnetised' and which not. When patients were observed to enter the 'crisis' at the suggestion that a tree had been magnetised rather than one that physically had been, they concluded that animal magnetism did not exist and that all its effects were produced by imagination, a theoretical basis which has continued to be important. Unfortunately, at the time, the commission concluded that, since animal magnetism did not exist, there was no basis on which these effects could be useful, despite some spectacular cures for conditions that orthodox medicine could not help. Following the demise of the theory of animal magnetism, theoretical and clinical thinking became focussed on the idea of the similarities to sleep, the name 'hypnosis', from the Greek for sleep being applied by James Braid in 1843 (Braid, 1843). Although practitioners such as the Abbé de Faria, John Elliotson and James Esdaile were still known as 'magnetisers' they had dispensed with the use of magnets and other paraphernalia and were using spoken suggestions and 'passes' over the bodies of their patients to produce an artificial somnambulism which sometimes allowed surgery to be carried out without distress to the patient.

The rejection of the theory of magnetism by Braid led to a furious debate between Braid and the 'magnetisers' focussed on the causes of the phenomena that they both produced in different ways. Braid stated in

1846.... "I attribute it to a subjective or personal influence, namely, that of the mind and body of the patient acting and re-acting on each other in a particular manner, from an intense concentration of inward consciousness of one idea, or train of ideas, which may, to a certain extent, be controlled and directed by others." (Braid, 1946) (p.36).

Contemporaneously, Elliotson founded the mesmeric journal 'The Zoist' and Esdaile reduced the mortality rate from surgery from the average 50% to 5% using mesmeric anaesthesia. However, these developments failed to bring hypnosis into the mainstream of medical practice in Britain, but Braid's theories were better received in France.

In the late 1800s theorising became split between the Paris and Nancy schools and a fierce debate ensued between them. Charcot, director of the Salpêtrière mental hospital in Paris was a neurologist and maintained that hypnosis was pathological in nature and virtually identical to hysteria, whereas Liebeault and the Nancy school were closely allied to Braid's theories. They emphasised the use of suggestion as the vital element in hypnosis and postulated that the hypnotic state enabled people to more readily accept suggestion (Simons et al., 2007) a theoretical position still held today. One member of the Nancy school went even further and rejected hypnotic induction maintaining that suggestion alone was equally effective (Gravitz, 1991).

# Individual Differences in Response to Hypnotic Procedures

The discussion of whether hypnotisability is a trait or property of the individual has early roots. According to animal magnetism, the effects are

produced by the flow of the universal fluid which is influenced by the magnetiser, but very early in its history some began to question this and postulate that the individual subjects themselves produced the responses. This variation in responses was noted by Faria in 1819 and he estimated that some 20% of the population was highly responsive (Simons et al., 2007, Gravitz, 1991).

#### Rapport

Rapport was recognised early as a prerequisite for the clinical use of techniques such as mesmerism and animal magnetism. Mesmer regarded it as essential and his followers continued in this belief (Gravitz, 1991). This close relationship with his patients was one cause of Mesmer's ostracism from the medical establishment with the Royal Commission producing a secret report which alleged impropriety between magnetisers (mainly men) and patients (mainly women). This idea was embraced by Freud who maintained that hypnosis was an eroticised dependent relationship. Rapport was also central to the work of the Nancy school of hypnosis and remains central to clinical hypnosis in the present.

#### **Current Theories of Hypnosis**

Despite a century of research, a single all encompassing definition of hypnosis is still lacking, despite many attempts (Green et al., 2005, Nash, 2005). The British Psychological Society uses the following definition:

'The term 'hypnosis' denotes an interaction between one person, the 'hypnotist', and another person or people, the 'subjects'. In this interaction the hypnotist attempts to influence the subjects' perceptions, feeling, thinking and behaviour by asking them to concentrate on ideas and images that may evoke the intended effects. The verbal communications that the

hypnotist uses to achieve these effects are termed 'suggestions'. Suggestions differ from everyday kinds of instructions in that they imply that a 'successful' response is experienced by the subject as having a quality of involuntariness or effortlessness. Subjects may learn to go through the hypnotic procedures on their own, and this is termed 'self-hypnosis'. (p.3) (2001)

Hilgard (1994) identified the responses which he called 'the domain

of hypnosis', in order to specify what behaviours could be attributed to

hypnotic response.

Alteration in Voluntary Muscles	Relaxation Paralysis of muscle groups Catalepsy
Alteration on Involuntary muscles, organs and glands	Changes in heart rate Lowering of blood pressure, alteration of blood flow to the capillaries Variations in respiratory rate Changes in the alimentary system Alteration in salivary flow and perspiration Changes in metabolism Anatomical and biochemical changes, e.g.,
Alterations of the senses	Anatomical and biochemical charges, e.g., bleeding, blistering, modification of allergic skin responses Changes in visual ability, positive or negative Changes in hearing abilities Olfactory and gustatory changes Tactile changes including alteration in pain sensation Paraesthesias
Somnambulism Illusions and Hallucinations	Positive and negative
Alteration of Memory	Sight, sound, taste, smell, touch, sensation (including pain) Post hypnotic amnesia (rarely spontaneous) Partial amnesia during hypnosis, e.g. for a name or number
Age Regression	Creation of false memories Not a literal reinstatement of the age regressed to.
Time distortion (Simons et al. 2007)	Usually underestimating time in hypnosis

#### Table 3 The domain of hypnosis

(Simons et al., 2007)

The main debate that has continued today is whether hypnosis constitutes a special state (trance) involving fundamental alterations in a person's state of consciousness, or whether hypnotic responding can be explained by more mundane social and psychological explanations such as beliefs, expectations, imaginative ability, compliance etc. The development of non-invasive ways of imaging brain function such as fMRI scanning have enabled researchers to add new ways of investigating this debate (Raz and Shapiro, 2002, Rainville et al., 1999), but as yet it is still not resolved (Lynn and Rhue, 1991, Kirsch and Lynn, 1995, Wagstaff, 1998, Lynn et al., 2005)

The second discussion is whether the ability to respond to hypnosis is a trait or property of the person, or whether it is modifiable by training or affected by situational factors is also on-going. There is no doubt that if individuals or groups are tested on standard scales of hypnosis their measured hypnotisability remains stable over many years (Hilgard, 1991), though this could be attributed to the similarity of the test situation and demand characteristics. There have been attempts to modify hypnotisability (Spanos et al., 1989, Spanos et al., 1990, Spanos et al., 1991) which have been tested, but these are not universally recognised to be effective.

### **Clinical Hypnosis**

Hypnosis has been investigated in many clinical areas of medicine, psychology and dentistry and meta analyses have found it to be a promising and useful adjunct to treatment although more well controlled randomised clinical trials are needed in all areas (Kirsch et al., 1995, Pinnell and Covino, 2000, Schoenberger, 2000, Cardena, 2000, Green and Lynn, 2000, Lynn et al., 2000, Milling and Costantino, 2000, Montgomery et al., 2000, Gold et al., 2007).

A difficulty in comparing may clinical trials of 'hypnosis' is the heterogeneity of techniques; either labelled or not labelled hypnosis;

individual or group; scripted or tailored to each individual and tape recorded or live.

For example, a recent Cochrane review of the evidence on hypnosis for smoking cessation concluded that there was not enough good evidence to show whether hypnosis is a useful treatment for smoking cessation or not (Abbot et al., 1998).

# Individual differences and hypnotisability in clinical hypnosis

There is much debate around the contribution of hypnotisability to the response to clinical hypnosis with some arguing strongly that formal measurement of hypnotisability is irrelevant in the clinical setting (Sutcher, 2008). The evidence is somewhat contradictory. There has been a recent meta-analysis of randomised controlled trials where hypnosis was active intervention in both medical, dental or mental health setting and where hypnotisability had been measured on a recognised scale. This study (although small – 10 studies included, 283 participants) found a small but significant relationship of hypnotisability to the success of the intervention and that the effects of hypnotic suggestibility could account for 6% of the variance in the outcomes. Nevertheless, the authors conclude that, given the length of time that such testing usually takes and the rather small effects found, hypnotisability assessments are not worth carrying out in clinical settings (Montgomery et al., 2011). They do admit that further studies should be carried out to confirm this for all populations and settings.

#### Hypnosis in Anxiety and Phobia

Hypnosis has been investigated in the treatment of anxiety disorders. Most of the literature consists of case reports although some controlled trials are reported. One compared hypnosis with meditation for the treatment of anxiety and found that both techniques were helpful in reducing self-rating, psychiatric assessment and systolic blood pressure. Those individuals who were high to moderate in hypnotisability improved more on both methods of treatment than those who were low hypnotisable (Benson et al., 1978). A small controlled study of hypnosis for phobias showed patients treated with hypnotherapy (using memory reformulation or ego-state procedures) showed a significant reduction of the phobias in a maximum of three sessions compared to a waiting list control group (Somerville and Jupp, 1992). In this study no relationship was found to hypnotisability. Some authors argue that hypnosis works in the relief of fears and phobias because of the use of desensitisation methods within the hypnotic context, rather than the use of hypnosis per-se (Cautela, 1966). This early discussion of the factors involved in the hypnotic treatment of phobias would probably be accepted today, with the alternative explanation that hypnosis is used as an adjunct to behaviour therapy techniques, rather than as a therapy in its own right. Others suggest that hypnosis facilitates behavioural methods as it allows access to otherwise repressed or state-bound memories relevant to the phobic reaction, thus combining behavioural and psychodynamic treatment methods (Bodden, 1991). The effects of hypnosis on memory have also been used to reconstruct memories of traumatic events, where the patient has such memories and believes them to have caused their phobia.

One case report describes a dental phobia which the patient believed had been caused by a childhood experience of having dental treatment forcibly carried out when her tooth was inadequately anaesthetised. She relieved the experience in hypnosis, but was assertive and threatened the dentist with violence if he did not give more anaesthetic. The case report alleges that this brought about complete relief from the dental phobia (Lamb, 1985). Whilst it is acknowledged that memories during hypnosis may not be historically truthful (Heap et al, 2001), this case used a memory of a childhood experience and used hypnosis to modify its effect on the patient. Needle phobia has also been treated by hypnosis, especially when invasive medical treatment would otherwise be difficult or impossible (Liossi and Hatira, 2003, Cyna et al., 2007). A recent Cochrane review included five studies using hypnosis to reduce procedure related pain and distress for needle-related procedures for children and adolescents and reports that hypnosis had the 'most positive evidence across several outcomes' and conclude that hypnosis may be an 'efficacious intervention' for reducing both pain and distress reported by the children themselves and also reduced behavioural measures of distress (Uman et al., 2006).

Treatment of examination anxiety and performance anxiety have also been reported (Stanton, 1993b, Stanton, 1993a) using a variety of techniques, including relaxation, 'dumping mental rubbish, success visualisations and the 'clenched fist technique' (Stein, 1963, Stanton, 1988a, Stanton, 1988b).

#### **Hypnosis in Surgical Procedures**

In the field of surgery hypnosis has been investigated as a method of preparation for surgery. When tested against oral pre-medication with oral

midazolam for children, hypnosis lowered anxiety scores in children scheduled for abdominal surgery between arrival in the department to applying the anaesthetic mask, whereas anxiety levels increased for the midazolam group. The use of hypnosis also seemed to reduce postoperative behavioural disturbances (Calipel et al., 2005). However, in this study the anxiety score was taken by nursing staff and it is unlikely that the nurse was blind to the treatment group.

Hypnosis has also been used to reduce anxiety and discomfort in a range of invasive medical procedures and shown to be effective in reducing drug use and pain following the procedure regardless of hypnotic susceptibility (Fick et al., 1999). It has also been shown to have beneficial effects during such procedures, reducing drug use in patient controlled IV analgesia and having the advantage over simple attention and reassurance that it improved haemodynamic stability in patients undergoing percutaneous vascular and renal procedures (Lang et al., 2000). In this latter trial involving 241 patients randomised to three groups patients received hypnosis, attention or standard care during the surgical session. Hypnosis patients differed from the attention group and the standard treatment group with less drug used, lower pain ratings and shorter time taken to complete the procedure (Lang et al., 2000)

One area of controversy is that of whether hypnotisability affects clinical outcome. Although some studies have measured hypnotisability and related it to outcome (Benson et al., 1978) most either do not measure susceptibility or suggestibility or if they do, it seems to be unrelated to the treatment outcome, or to the nature of the patient's experience (Fick et al., 1999).

A second area of controversy is whether 'hypnosis' is called 'hypnosis', or whether other labels are acceptable. In some studies, the addition of the term 'hypnosis' to a pre-existing technique has enhanced the effectiveness of the technique, whereas other investigators have argued that the term may inhibit patients (Hendler and Redd, 1986) by its unfamiliarity and have simply requested their patients to imagine or experience (Fick et al., 1999). However, a meta-analysis of hypnosis (defined as hypnosis) with unselected (for hypnotisability) surgical patients including 20 papers showed medium to large average effect sizes and concluded that, on average, 89% of surgical patients benefited from adjunctive hypnosis compared to patients in control conditions (Montgomery et al., 2002).

#### Hypnosis in Dentistry

There is a massive literature on hypnosis in dentistry, but unfortunately much of it is confined to single case reports (Eitner et al., 2006a), review articles (Patel et al., 2000, Kent, 1986a), or introduction to the use of hypnosis (Shaw and Niven, 1996, Simons, 1985). Kent (1986a) suggests that dentists who use hypnosis may be reluctant to engage in controlled trials as they have had so much success with hypnosis.

Hypnosis for pain control is a large area of research, which shows promise for the future, a recent review suggesting that hypnosis relieves pain for most people most of the time (Montgomery et al., 2000). Most studies are not within the dental context, but some have used electronic pulp stimulation as an experimentally induced pain stimulus (Barber and Mayer, 1977, Houle et al., 1988, Sharav and Tal, 1989). In the Houle et al study,

pain reductions under hypnotic and relaxation conditions were compared, as were pain caused by pulp stimulation and cold pressor pain. There were no differences shown between suggestions give following hypnotic induction and following progressive muscular relaxation, but greater reductions, both in strength and unpleasantness of pain sensations was greater for pulp stimulation than for cold pressor pain. The authors suggest that laboratory pain stimuli should be developed which relate to the clinical pain to be studied. The mechanisms of hypnotic pain control are becoming better understood thanks to the use of brain scanning techniques such as fMRI scans, at least in those individuals who are highly susceptible to hypnosis (Crawford et al., 1998, Gruzelier, 1998)

The control of gagging using hypnosis has also been reported, but hypnosis is seen as an adjunct to facilitating specific treatment methods for this problem (Barsby, 1994). A review of the literature suggests that hypnosis may be useful, but cites only case report and review articles to support this (Bassi et al., 2004).

Control of bleeding and peripheral circulation has been claimed to be another advantage of hypnosis in dentistry leading to less blood loss following surgical procedures, but this has not been substantiated by experimental work that includes physiological measurements (Clark and Forgione, 1974). However, some clinical studies have demonstrated less blood loss following maxillofacial surgery particularly when preoperative hypnotic suggestions were given, this was combined with lower blood pressure, so the non-specific effects of hypnosis in lower arousal may be

responsible for the effect, rather than direct control of peripheral circulation (Enqvist et al., 1995a).

Hypnosis for the treatment of bruxism has been reported in the literature, several case studies (Goldberg, 1973, LaCrosse, 1994), one pilot study (Clarke and Reynolds, 1991) and one study including objective measurement of a reduction in masseter activity following hypnosis (Gow, 2005) suggest that hypnosis may be useful in this area.

#### Hypnosis for Dental Anxiety and Phobia

There is a large and growing literature on the use of hypnosis in the alleviation of dental anxiety and phobia alongside a little evidence that phobias and hypnotic susceptibility may be related – both dental and other phobic patients seeming to score higher in tests of hypnotisability than the general population (Frankel and Orne, 1976, Gerschman, 1989, Gerschman and Burrows, 1997). Many single case reports form part of this literature. They use a variety of methods and techniques and are therefore of interest to clinicians, but cannot be considered evidence for its effectiveness. For example techniques aimed to alter the content of traumatic memories of dental treatment (Baker and Boaz, 1983) have been described. Other papers refer to case study series, Fabian and Fabian (1998) report the use of hypnosis in a group of needle phobic patients who had previously exhibited needle related collapse. Hypnosis for dental anxiety (consisting of throwing boxes representing their anxiety from a moving vehicle of their choice) resulted in reduction of anxiety in all cases and total lack of previous anxiety symptoms in 8 out of the 12 cases. In a large case study series (209 operations in 174 patients who expressed an interest in hypnosis

combined with local anaesthesia for oral and maxillofacial surgery) 94.3% of operations were considered successful on the part of both the patient and the surgeon (Hermes et al., 2005). However, this was determined by interview following surgery and no objective measures of anxiety reduction are reported. An earlier controlled study (Ghoneim et al., 2000) in which a similar process was used in combination with conscious sedation (midazolam, fentanyl and 50% nitrous oxide), the patients who received the tape recorded hypnosis in the week prior to surgery showed a significantly lower increase in anxiety (STAI-state) than those who did not receive the tapes.

The physiological changes in patients undergoing implant placement under local anaesthesia and hypnosis in both high fear and low fear individuals has been investigated (Eitner et al., 2006b). Although this is a small study (n=17 in the experimental group), the randomisation and assignment to conditions is unclear and has a variety of control conditions and group sizes which are not equivalent to the treatment received by the experimental group, it does show a general decrease in physiological arousal when hypnosis is used, compared to the baseline state (systolic and diastolic blood pressure, respiration rate and pulse rate). The authors also note a change (a hemispheric shift from left to right hemispheres followed by a shift from anterior to posterior brain segments) in EEG recordings in line with other studies. In addition, the changes were more pronounced in those patients who scored higher on the DAS before treatment.

Physiological changes have also been investigated during the administration of local anaesthetic to children with and without hypnosis. Twenty nine

children were assigned to hypnosis or no hypnosis conditions by a coin flip and significant differences were found in pulse rates during the procedure, the hypnosis group showing a decrease whilst the non-hypnosis group's pulse rates increased (Gokli et al., 1994).

Another anxiety-producing treatment for many patients who accept other dental treatment without disproportionate anxiety is endodontics. One author had investigated hypnosis, either combined with, or compared to meditation techniques in endodontic patients and reports reductions of anxiety and enhanced satisfaction with treatment when both techniques are used either separately or in combination (Morse et al., 1977, Morse, 1976, Morse et al., 1981). However, these are mostly small case series, with no randomisation or control group (with the exception of Morse et al (1981) where 2 control groups – LA alone and LA with nitrous oxide sedation were compared to hypnosis and meditation. This study included an interesting physiological measure – saliva flow – which was significantly increased in line with decreased reported anxiety.

Hypnosis for implant placement surgery has been shown to affect neurophysiologic parameters (heart rate, BP, respiration rate) with the greatest benefit for patients reporting high anxiety for dentistry (Eitner et al., 2006b)

Hypnosis for dental anxiety has been compared to other treatments. Moore et al (2002) compared hypnotherapy to two forms of systematic desensitisation (video and direct exposure) and group therapy and found that there was no difference between the groups in the short term with all treated patients showing reduced dental anxiety and improved trust following

specialised treatment. However, in the long term (3years) follow up, the hypnosis group showed the greatest attrition with nearly 50% of the group having dropped out or not seeking regular dental treatment. Those who did seek long-term care showed reductions in dental anxiety equivalent to those in the other treatment groups. One problem with this study is that it treated hypnosis as a therapy in its own right, rather than as an adjunct to an established therapeutic modality. Similarly, hypnosis compared to individual behavioural treatment did not produce as much decrease in dental fear (Hammarstrand et al., 1995)

Chapter 2 presents the qualitative results of a systematic review of randomised controlled clinical trials in this area.

#### Hypnosis methods used for dental anxiety and fear

A variety of hypnotic methods have been described to reduce dental fear and anxiety, most not being described in sufficient detail to be reproducible. A form of 'Ericksonian' hypnotherapy was used by Moore et al (2002) including multiple types of suggestions e.g. trance deepening at the sound of the drill, imagery of a wall representing dental anxiety, dissociation and age regression. This is in contrast to the view of hypnosis as an adjunct to therapy where it shows promising results (Schoenberger, 2000). Other techniques include; techniques aimed to alter the content of traumatic memories of dental treatment (Baker and Boaz, 1983, Kent, 1986a); imagery suggestions (Fabian and Fabian, 1998) and hypnosis combined with other techniques such as systematic desensitisation (Fabian, 1996). Tape recorded suggestions have been shown to be effective particularly in the field of oral surgery (Ghoneim et al., 2000, Hermes et al., 2005).

#### **Conclusions**

Despite the large literature on hypnosis and dentistry, it is not possible to draw firm conclusions on its effectiveness at the present time. Further large scale trials will be needed before firm recommendations can be made to change current practices. However, the current knowledge base is encouraging and should stimulate further studies in the area.

### **Inhalation Sedation Hypnosis and Suggestion**

Inhalation sedation has been termed 'psycho-sedation' rather than true sedation in terms of a state of depression of the central nervous system. Response expectancy is a term which means the expectance of the occurrence of responses outside the control of the individual. These may be emotions, symptoms pain etc. (Kirsch, 1985). They have been shown to be important in the placebo response to drugs as well as responses to more psychologically based interventions. The following section outlines their role in IHS and the actions of nitrous oxide and in response to hypnosis.

# Influencing the Actions of Inhalation Sedation by

#### Manipulating Expectancy

The effects of nitrous oxide/oxygen mixtures seem to be susceptible to manipulation by changing the expectations of the person who inhales it. In a series of experiments Dworkin and co-workers (Dworkin, 1986, Dworkin et al., 1983b, Dworkin et al., 1984) manipulated the analgesic effects of nitrous oxide in volunteers both in laboratory and clinical contexts. In these experiments the pain stimulus was tooth pulp shock delivered to a healthy central incisor and participants were report their absolute sensation threshold, pain threshold and pain tolerance at baseline and whilst breathing various concentrations of nitrous oxide (Dworkin et al., 1984). Two levels of information were provided, low information which simply gave information about the procedure of the experiment and a high information condition which included information about nitrous oxide's pain-reducing effects and how these might be produced. Results showed that the high information group reported significantly higher thresholds on all three measures and at all three concentrations of nitrous oxide (15%, 30% and 45%).

In a follow-up to this study, the hypothesis that pain sensitivity could be increased by altering expectancy was tested. It has already been shown that pain perception is altered by expectancy and context in the absence of pharmacological agents (Dworkin and Chen, 1982), but this study aimed to reverse the expected analgesic properties of 33% nitrous oxide. Participants were told that some drugs known for their sedative properties could also enhance creativity and to produce an altered state of consciousness allowing people to have heightened sensitivity.

Under these conditions, the expected increase in absolute sensation threshold, pain threshold and pain tolerance levels was not found, and in the majority of cases participants showed decreased levels on all three measures, in other words, they showed hyperalgesia, rather than the expected analgesia. This study was small (11 participants) but the effects were large enough that this finding was statistically significant.

This study was replicated with a group of dental patients in a clinical setting, although the pain stimulus was retained as the experimental tooth pulp shock. The patients demonstrated a similar pattern of responses, albeit not as marked as the experimental participants (Dworkin et al., 1986). Anxiety levels seemed to be unaffected by the pain perception manipulations.

# Influencing the Actions of Hypnosis by Manipulating Expectancy

Response expectancies are proposed by some theorists to be determinants of hypnotic responding. A weak and a strong version of the response expectancy hypothesis have been proposed (Spanos et al., 1993). The weak version puts response expectancy as one of a number of variables affecting hypnotic responding, whereas the strong version suggests that expectancies directly influence it (Kirsch, 1985).

Early in hypnosis research Martin Orne (1959) demonstrated that manipulating expectancies of the role of the good hypnotic subject resulted in changes in behaviour under hypnosis, specifically that subjects led to believe that spontaneous arm catalepsy was typical in hypnosis were much more likely to demonstrate this behaviour when they were later hypnotised. Experiments designed to test the expectancy hypothesis in relation to hypnotisability have had mixed results. Wickless & Kirsch (1989) found that manipulations aimed to convince participants that they were highly hypnotisable resulted in higher scores on hypnotisability scales than participants who did not receive these interventions. The hypnotisability

scores were stable over time, even after participants had been told that they had been deceived. This result was challenged (Benham et al., 1998) who failed to replicate the results. Spanos et al (1993) found a fan-shaped rather than a linear relationship between expectancy and hypnotic responding, suggesting that expectancy alone cannot explain responsiveness. There is evidence that the word 'hypnosis' itself acts to increase responsiveness to suggestions when compared to the same induction procedure labelled 'relaxation' (Gandhi and Oakley, 2005).

# Influencing the Actions and Effectiveness of Inhalation Sedation using Hypnosis

In papers which advise clinicians on the use of inhalation sedation or relative analgesia it is often recommended that reassuring 'semi hypnotic' suggestions are necessary to produce effective sedation. Roberts (1990) refers to 'the triad of elements in relative analgesia'; the mixture of gases, failsafe equipment and semi-hypnotic suggestion. Coulthard and Craig (1997) recommend hypnotic suggestion including reassurance and encouragement. Despite this, evidence for these recommendations is sparse and, in addition, papers investigating the effectiveness of Inhalation Sedation or RA sedation often refer to a 'standard technique', but do not specify what this means in terms of the verbalisations or suggestions given during the procedures.

One case study series has been published which specifically addresses the addition of hypnosis to inhalation sedation (Shaw and Welbury, 1996). This paper describes the treatment of 20 children who failed to accept treatment

with inhalation sedation for dental extractions. Here, hypnosis was explicitly added and children were selected provided they attained eye closure and responded to imagery suggested by the clinicians. The children were aged 6-14, and 20 were able to respond in this way, so treatment was continued. Inhalation sedation followed the initial induction and was continued for a further 10 minutes before the child was asked if the dentist could look in their mouths. If the child consented to this, the treatment and the imagery suggestions continued until the extractions were complete, then a standard alerting procedure followed with a count of one to five. Of the 20 children who initially responded, 16 completed their treatment. The other 4 were referred for general anaesthesia. A further case report describes the successful combination of hypnosis followed by treatment with IHS combined with hypnosis in the treatment of an adult male (Thompson, 1994).

Other papers combining hypnosis and sedation have used hypnosis combined with intravenous sedation (Faymonville et al., 1995, Wilson, 1996, Faymonville et al., 1997, Lang et al., 2000), , Dyas, 2001, Lang and Rosen, 2002,) intra-muscular ketamine (Lu, 1994) and a combination technique involving intravenous sedation and 50% nitrous oxide (Ghoneim et al., 2000). Several studies showed a reduction in patient's need for one or more intravenous drugs (Lang et al., 2000, Faymonville et al., 1997, Dyas, 2001). Two showed reductions in measured anxiety (Ghoneim et al., 2000, Wilson, 1996). One showed a cost advantage to using hypnosis (Lang and Rosen, 2002) and one noted that the procedure was cost effective (Ghoneim et al., 2000).

#### Influencing the Actions of Hypnosis using Nitrous Oxide?

Langa (1968) reports that the use of nitrous oxide relative analgesia could be used to aid the induction of hypnosis. He states that, in the experience of two colleagues, hypnotic induction was almost immediate and that the effects were superior to nitrous oxide alone producing more muscle relaxation, euphoria and reduction of conscious awareness. As in the early description of a combined technique (Schupp, 1997) the nitrous oxide was then turned off and the session continued with hypnosis alone. Langa reports two cases from a series of 10 unhypnotisable subjects who apparently responded as if they were highly hypnotisable with the aid of nitrous oxide and hypnotic induction. He concludes that this warrants further investigation as relative analgesia makes it possible to hypnotise almost all patients. In another early report (Bingham, 1964) several cases of the combination of the two techniques are described.

In 1979 a small study indicated that the administration of therapeutic concentrations of nitrous oxide/oxygen mixtures seemed to enhance the uptake of hypnotic suggestions. However, the study was very small and had some methodological defects. (Barber et al., 1979) The study is cited in journal articles to support the use of suggestion or hypnosis as part of the technique of inhalation sedation (for example Roberts, (1990)). The authors aim was to test whether nitrous oxide/oxygen mixtures would produce gains in suggestibility to aid clinicians to use the technique carefully in order to give useful therapeutic suggestions rather than careless suggestions which may be damaging. The study involved 20 volunteers (students) randomised into two groups (the randomisation procedure is not reported). One group

received titrated doses of nitrous oxide/oxygen given by an anaesthetist who gave 10% nitrous oxide rising by 5% increments until a "baseline" level of sedation was obtained. This involved paraesthesia, generalised warmth and sedation without disorientation, although we are not told how this was tested. As the experiment was double blind, the second group receiving 100% oxygen were given the same information on the expected effects of nitrous oxide and the anaesthetist gave the impression to both the participant and the experimenter that nitrous oxide concentrations were being increased. Standardised suggestions were given, by reading from a script, for analgesia (for pressure pain in the right leg compared to the left), compulsive behaviour (choosing a red pen to sign a form) and amnesia (the participant would not remember any of the suggestions until a cue word was given). These suggestions are usually regarded as 'hard' suggestions response to them indicating high suggestibility (Council, 1999, Hilgard and Hilgard, 1983). The results showed a higher percentage response in the nitrous oxide group than in the oxygen group, and overall the response of the nitrous oxide group was significantly greater than the oxygen group. There was no baseline measure of waking or hypnotic suggestibility, although the Stanford Hypnotic Clinical Scale (Hilgard and Hilgard, 1983) was given after the experiment and it is stated that there was no relationship between the results and participant's response during the experiment, no data are presented in the paper to support this.

A recent experimental study (Whalley and Brooks, 2009) aimed to test whether the inhalation of nitrous oxide changes imaginative suggestibility and imagery vividness. Thirty participants had two test sessions, one

breathing nitrous oxide and one using a sham procedure (breathing through the same nose-piece but with no  $N_2O$  flowing and the air intake valve open). Half the participants breathed 25%  $N_2O$  on the first visit and half on the second. The smell of the gas was disguised by a scented nose-piece and only 11 participants guessed correctly which session they had received the gas. Results indicated that breathing the  $N_2O$  increased both imaginative suggestibility and imaginative ability. Although these changes are strongly related to hypnotic suggestibility, participants were told that this experiment was NOT about hypnosis.

#### Summary

This overview has shown that dental anxiety is a significant problem affecting many people. People who are anxious about dentistry are less likely to attend for regular dental care, and when they do, they are more difficult to treat. Behavioural and psychological methods have been used to help to reduce this, with CBT being judged the most successful. Sedation is often the major treatment modality offered for anxious patients, but may not be the most successful in the long term rehabilitation of these patients. Hypnosis has been used for many years, by a minority of dentists, but the evidence for effectiveness is mixed. Inhalation sedation has also been used and whilst its effectiveness has been confirmed in anxious children, there are few studies that assess its use in adults.

The combination of hypnosis and IHS has been suggested, but so far evidence is lacking.

This project will go on to investigate the evidence for the use of hypnosis in the reduction of dental anxiety and present the results of two studies aiming to investigate whether the addition of hypnosis to IHS can reduce anxiety in an experimental situation.

# **CHAPTER 2**

# **Hypnosis for Alleviation of**

# **Anxiety in Adults Undergoing**

# **Dental Treatment**

**A Systematic Review** 

### Part 1

# **A Cochrane Protocol**

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#### **Background**

#### **Description of the condition**

Anxiety towards dental treatment is widespread in the population. The latest adult dental health survey in the UK reported that 36% of participating adults had moderate dental anxiety and 12% extreme dental anxiety (NHS information Centre 2010). It is also a global problem, although published figures vary throughout the world. It is also possible that much severe anxiety goes unreported as sufferers may not attend the dentist due to their fear. Dental anxiety and fear of dentistry can be considered facets of the same problem and the terms can be used interchangeably in both lay and scientific discourse.

Dental anxiety is unpleasant for sufferers. There are physical, psychological and behavioural consequences of anxiety and it may lead to neglect of the dentition. Physical effects include shaking, sweating and increased heart rate, sometimes at the thought of dental treatment. Psychological effects include feelings of low self esteem, shame, fear, etc. Behavioural changes include the avoidance of dental appointments and in severe cases sufferers may avoid mention of dentists in television, film, newspapers and conversation.

For dental care professionals anxious patients are an important cause of stress as it is often difficult to provide treatment for such individuals. In addition, anxiety may lead patients to cancel their appointments or simply fail to attend their appointments on the day.

Both pharmacological and psychological approaches to overcoming fear of dental treatment are widely reported in the literature, but no one approach is acceptable or applicable to all (de Jongh 2005). Behavioural methods have been shown to be effective and there is some evidence that long term improvement is more likely in patients who receive such methods compared to those who receive pharmacological interventions (Aartman 2000).

#### **Description of the intervention**

Hypnosis has been proposed as a potential mode of treatment in the alleviation of dental anxiety and has been used by dentists since the first reports of tooth extraction under hypnosis in the 1800s. Hypnosis in dentistry has been used in many ways. These include as a method of pain control, to control or reduce anxiety towards treatment, to treat dental and needle phobia and to assist in changing habits detrimental to oral health such as smoking (Simons 2007).

According to the British Psychological Society:

"The term 'hypnosis' denotes an interaction between one person, the 'hypnotist', and another person or people, the 'subjects'. In this interaction the hypnotist attempts to influence the subjects' perceptions, feeling, thinking and behaviour by asking them to concentrate on ideas and images that may evoke the intended effects. The verbal communications that the hypnotist uses to achieve these effects are termed 'suggestions'. Suggestions differ from everyday kinds of instructions in that they imply that a 'successful' response is experienced by the subject as having a quality of involuntariness or effortlessness. Subjects may learn to go through the hypnotic procedures on their own, and this is termed 'self hypnosis''' (page 3) (British Psychological Society 2001).

Hypnosis is not regarded as a treatment in its own right, but should be seen as an adjunct to treatment methods that practitioners use already (British Psychological Society 2001; Simons 2007).

#### How the intervention might work

Hypnosis has been used to treat anxiety in many contexts not just dentistry. It has been evaluated as an adjunct to cognitive behavioural therapy and considerable benefit was demonstrated in a number of conditions with obesity studies having the largest effect sizes in one meta-analysis (Kirsch 1995) and long term follow-up (Schoenberger 2000). Benefit has also been demonstrated in anxiety disorders, although further well designed studies are needed (Schoenberger 2000).

There may be a number of mechanisms by which hypnosis could relieve anxiety about dentistry. These may be specific to hypnosis or non-specific effects of the therapeutic situation using hypnosis.

During dental treatment, hypnotic suggestions for relaxation may ameliorate anxiety by reducing autonomic arousal. Hypnotic relaxation is used here in a similar way to reciprocal inhibition (Wolpe 1958).

Hypnosis is dependent upon good rapport between hypnotist and subject and the dentist/patient relationship is an important modifying factor in anxiety, a poor relationship increasing the likelihood of a patient becoming anxious. In a survey of Danish adults, anxious people were more likely to have negative experiences of dentists' behaviours (Moore 1993). Hypnotic procedures could make dental treatment more acceptable which may challenge patient's negative beliefs about dentistry. This could include using techniques aiming to help patients to reformulate memories of traumatic experiences of dental treatment with the help of appropriate intervention by the therapist (British Psychological Society 2001). Fear of pain is one of the reasons that patients may be anxious and hypnosis is a well established method of pain control (Montgomery 2000). Hypnosis can potentiate the use of imagery and can be used as an adjunct to techniques such as systematic desensitisation, modelling and other behaviour modification techniques (Simons 2007).

People having hypnotic experiences such as pain sensation show patterns of brain activity closely corresponding to those found when the person has the same experience in reality. It is possible that suggestions to experience other effects, for example relaxation and comfort may reduce anxiety in similar ways (Derbyshire 2004).

#### Why it is important to do this review

There is published work on the effectiveness of hypnosis as a treatment for dental anxiety, including clinical trials comparing hypnosis to other behavioural methods and to normal treatment protocols (for example Eitner 2006b; Hammarstrand 1995; Moore 2002) but so far, the evidence for its

effectiveness has not been subject to systematic review. As the public become more interested in complementary approaches in health care in general it becomes more important than ever that evidence is evaluated. Hypnosis is regarded as a benign procedure. It is recommended that it is used within the expertise of the hypnotist - hypnosis should only be used to treat conditions that the professional would treat without hypnosis. In addition, the British Psychological Society recommends that only those with considerable experience in treating such patients should use it with psychotic patients (British Psychological Society 2001).

Many researchers contend that hypnosis cannot evoke psychotic states such as schizophrenia and that a minority of people report such things as headaches, dizziness, nausea or stiff necks, with a much larger percentage reporting positive effects (Lynn 2000).

However, there are documented instances of adverse effects of the use of hypnosis in clinical and experimental contexts. Most are mild and of short duration, but practitioners should have appropriate training in order to recognise and deal effectively with such occurrences (Gruzelier 2000). Costs to the patient will vary according to the healthcare system in place, but one US study showed that using hypnosis as an adjunct to sedation may reduce costs (Lang 2002).

Hypnosis is of international interest, the International Society of Hypnosis (ISH) has constituent societies in 19 countries worldwide (ISH 2013). A similar review of hypnosis in dentistry for children has recently been published (Al-Harasi 2010), so a corresponding review for adults would be desirable.

#### **Objectives**

To determine the effects of hypnosis (with or without conscious sedation or prior to or following general anaesthesia) in reducing anxiety towards dental treatment.

#### **Methods**

#### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs)

We will exclude cross-over trials

#### Types of participants

Participants will be adults seeking or undergoing dental treatment. No restrictions will be placed on trials including patients with co-morbidities including other psychological disorders, however, we will include such factors in the characteristics of included studies to allow a decision to be made on whether this could be a confounder.

#### Types of interventions

Hypnosis can be used as a stand-alone intervention or as an adjunct to other pharmacological and non-pharmacological treatments for dental anxiety. In order to examine as much evidence as possible both methods of use will be included in this review. Interventions will be any hypnotic technique with or without the addition of pharmacological sedation or general anaesthesia. The comparisons will be no treatment or usual care, placebo, sedation, general anaesthesia, other behavioural techniques.

As hypnosis can be used as an adjunct to other anxiety reduction techniques, studies will be included in which hypnosis is used adjunctively to other pharmacological and behavioural techniques. In such studies, comparisons will be the technique without the addition of hypnosis.

Trials comparing different types of hypnotic treatment, for example live versus tape recorded hypnosis, will be included.

Trials of hypnosis associated with local anaesthesia will also be included.

#### Types of outcome measures

#### **Primary outcomes**

- Self reported dental anxiety measured by anxiety scales or state anxiety scales.
- Physiological measures of anxiety (including dental anxiety), heart rate, heart rate variability, blood pressure, skin conductance or any other recognised measure.

It is possible that these may not have been the primary outcome of the study itself as studies often include measurement of anxiety in studies aimed primarily at other dental issues, e.g. pain.

#### Secondary outcomes

- Ability to accept dental treatment this may be measured by questionnaire or be indirectly assessed by successful completion of planned dental treatment.
- Patient satisfaction with hypnosis or dental treatment or both.
- Reduction in dosage of any sedative agent used.
- Ease of carrying out treatment this assessment should be made by the dentist carrying out the dental treatment who may not be the same person as the hypnotist.
- Adverse effects.

#### Search methods for identification of studies

#### Electronic searches

For the identification of studies included or considered for this review, detailed search strategies will be developed for each database searched. These will be based on the search strategy developed for MEDLINE (Appendix 1) appropriately revised for each database.

We will search the following databases:

- Cochrane Oral Health Group's Trials Register (whole database)
- Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, current issue)
- MEDLINE via OVID (1946 to present)
- EMBASE via OVID (1980 to present)
- PsycINFO via OVID (1806 to present)
- CINAHL via EBSCO (1980 to present)
- AMED via OVID (1985 to present).

The MEDLINE search will combine the subject search with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (2008 revision) (as published in box 6.4c in the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0, updated March 2011) (Higgins 2011). The searches of EMBASE and PsycINFO will be combined with the Cochrane Oral Health Group's filters for identifying randomised controlled trials.

#### Searching other resources

We will search the following databases for ongoing trials:

- ClinicalTrials.gov (http://www.clinicaltrials.gov)
- The metaRegister of Controlled Trials (http://www.controlledtrials.com).

We will handsearch the following journals:

- Contemporary Hypnosis (2000 to present)
- International Journal of Clinical and Experimental Hypnosis (2000 to present)
- American Journal of Clinical Hypnosis (2000 to present)
- Australian Journal of Clinical & Experimental Hypnosis (2000 to present).

The reference lists of all eligible trials will be checked for additional studies. Specialists in the field known to authors will be contacted for any unpublished data.

#### Data collection and analysis

#### Selection of studies

At least two review authors will screen the titles and abstracts from the electronic searches to identify potentially eligible studies which require further evaluation to determine whether they meet the inclusion criteria for this review. Full text copies of all eligible and potentially eligible studies will be obtained and these will be further evaluated in detail by two review authors to identify those studies which actually meet all the inclusion criteria. From this group, those studies which do not meet the inclusion criteria will be recorded in the excluded studies section of the review and the reason for exclusion will be noted.

Disagreements will be resolved by discussion.

We will include all studies meeting the selection criteria in this review regardless of quality.

Articles in languages other than English will be assessed by their abstracts, where possible, and if they appear to be potentially eligible, the full text of the article will be translated.

#### Data extraction and management

Two review authors will extract information relevant to the objectives and outcome measures into a specially designed data extraction form independently and in duplicate. Any disagreements will be resolved by discussion. We will not be blinded to the journal of publication or the author(s) of the paper.

The following data will be extracted.

- Study design: RCT number of arms.
- Conducted in (country).
- Number of centres.
- Recruitment period.
- Funding source.
- Inclusion criteria.
- Exclusion criteria.
- Number of patients randomised.
- Number of patients evaluated.
- Treatment interventions including methods and duration.
- Control interventions including methods and duration.
- Numbers of patients in each group.
- Primary outcomes of trial and time(s) measured.
- Secondary outcomes of trial and time(s) measured.
- Was there a sample size calculation.
- Duration of follow-up.
- Comparisons at baseline.
- Any other issues.

#### Assessment of risk of bias in included studies

All studies meeting the selection criteria will be included in this review regardless of quality.

Risk of bias will be assessed using the methodology set out in chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). Included trials will be assessed for.

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and personnel (although it is recognised that this may not be possible due to the nature of the interventions).
   Judgement will be made as to whether non-blinding would affect the outcome and therefore constitute a risk of bias even where blinding is not possible.
- Incomplete outcome data.
- Selective reporting.
- Other sources of bias.

Trials will be assessed for risk of selection bias and allocated to one of the following groupings.

- Low risk of bias adequate concealment of the allocation (e.g. sequentially numbered, sealed, opaque envelopes or centralised randomisation).
- Unclear risk of bias uncertainty about whether the allocation was adequately concealed (e.g. where the method of concealment is not described or not described in sufficient detail to allow a definite judgement).
- High risk of bias inadequate allocation concealment (e.g. investigators knew in advance what the allocated assignment of the next participant would be).

For performance bias, judgement will be made on whether blinding of participants and study personnel is possible and if not, whether this produces a low, high or unclear risk of bias.

Detection bias in trials of hypnosis has similar issues, it is not always possible to blind outcome assessors to the intervention provided. Judgement will be made as above for performance bias.

Attrition bias will be addressed by examining missing data and drop-outs from the trials and reported as above using the criteria in chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

Selective reporting will be assessed and reported using the criteria in chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

Other sources of bias will be assessed as above.

#### Measures of treatment effect

Levels of anxiety measured by anxiety scales will be treated as continuous data and will be reported as mean and standard deviations. Physiological measures will be considered similarly. Dichotomous outcomes are possible such as completion of planned treatment or adverse effects. Adverse effects will be reported as number occurring with a risk ratio if necessary. Completion or not of planned treatment will be reported as a risk ratio.

#### Unit of analysis issues

It is likely that studies will have used heterogeneous outcome measures including a variety of different scales.

It is unlikely that cluster randomised trials or multiple arm studies exist in this area, but repeated measures are commonly used. In these cases several different outcomes will be defined, based on different times of measurement and analysed separately as recommended by chapter 9 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

#### Dealing with missing data

Trial authors will be contacted to attempt to retrieve missing data where necessary.

#### Assessment of heterogeneity

Heterogeneity in the results of trials will be assessed where appropriate, by inspection of a graphical display of the results and by formal tests of heterogeneity. Sources of heterogeneity are anticipated to be patient characteristics, outcome measures and the nature of the intervention and control groups.

#### Assessment of reporting biases

If there are sufficient numbers of trials, publication bias will be assessed according to the recommendations on testing for funnel plot asymmetry as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

#### Data synthesis

We will only conduct a meta-analysis if there are studies of similar comparisons reporting the same outcome measures. We will combine risk ratios for dichotomous data and mean differences for continuous data using fixed-effect models unless there are more than three studies in the metaanalysis.

#### Subgroup analysis and investigation of heterogeneity

Subgroup analysis may be carried out if sufficient data are available based on:

- initial anxiety levels on outcomes (e.g. dental phobia versus dental anxiety)
- the effect of the addition of hypnosis to sedation
- the effects of different dental treatments (e.g. oral surgery versus restorative treatment)
- the use of local anaesthetic versus no local anaesthetic.

#### Sensitivity analysis

Providing there are sufficient included trials, sensitivity analysis based on studies at low risk of bias will be undertaken.

#### Presentation of main results

A summary of findings table will be developed for the primary outcomes of this review using GRADEPro software. The quality of the body of evidence will be assessed with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates, the risk of publication bias and the magnitude of the effect. The quality of the body of evidence for each of the primary outcomes will be categorised as high, moderate, low or very low.

## Appendix 1

#### MEDLINE (OVID) search strategy

1. exp Dentistry/

2. (dental\$ or dentist\$ or "oral surg\$" or orthodont\$ or pulpotom\$ or

pulpect\$ or endondont\$ or "pulp cap\$").mp.

3. ((dental or tooth or teeth) and (fill\$ or restor\$ or extract\$ or remov\$ or"cavity prep\$" or caries or carious or decay\$)).mp.

4. ("root canal therapy" or "root canal treatment" or "endodontic\$").ab,sh,ti.

5. ((dental adj3 implant\$) or (tooth adj3 replant\$")).ab,sh,ti.

6. 1 or 2 or 3 or 4 or 5

7. Hypnosis, Dental/

8. exp Hypnosis/

9. exp Hypnosis, Anesthetic/

10. "Imagery (Psychotherapy)"/

11. Relaxation Therapy/

12. (autosuggestion or auto-suggestion).mp. [mp=title, original title,

abstract, name of substance word, subject heading word, unique identifier]

13. hypno\$.ab,ti.

14. "autogenic\$ train\$".mp. [mp=title, original title, abstract, name of

substance word, subject heading word, unique identifier]

15. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14

The above subject search will be combined with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (2008 revision) (as published in box 6.4.c in the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 updated March 2011) (Higgins 2011).

- 1. randomized controlled trial.pt.
- 2. controlled clinical trial.pt.
- 3. randomized.ab.
- 4. placebo.ab.
- 5. drug therapy.fs.
- 6. randomly.ab.
- 7. trial.ab.
- 8. groups.ab.
- 9. or/1-8
- 10. exp animals/ not humans.sh.
- 11. 9 not 10

#### Contributions of authors

Catherine Potter, Paul Coulthard, Richard Brown and Tanya Walsh wrote the protocol and will complete the review (protocol draft, acquisition of trial copies, trial selection, data extraction, data analysis, data interpretation, review draft and update draft).

#### **Declarations of interest**

Catherine Potter: no interests to declare. Paul Coulthard: no interests to declare. Richard Brown: no interests to declare. Tanya Walsh: no interests to declare.

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Disclaimer:

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health

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Note that the Cochrane reference style is used here.

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NHS information Centre 2010

The NHS Information Centre, Dental and Eye Care Team. The Adult Dental

Health Survey 2009 - first release. Available from www.ic.nhs.uk/statistics-

and-data-collections/primary-care/dentistry/adult-dental-health-survey--

2009-first-release. Schoenberger 2000

Schoenberger NE. Research on hypnosis as an adjunct to cognitive-

behavioral psychotherapy. International Journal of Clinical and

Experimental Hypnosis 2000;48:154-69.

Simons 2007

Simons D, Potter C, Temple G. Hypnosis and Communication in Dental

Practice. New Malden: Quintessence Publishing, 2007.

Wolpe 1958

Wolpe J. Psychotherapy by Reciprocal Inhibition. Stanford University Press, 1958.

# Part 2

# **Results Discussion and Conclusions**

This section presents the qualitative section of the review. It has not yet been published. Statistical input will be sought, although it is unlikely that meta-analysis will be possible. It will then be submitted as a Cochrane Review within the next year. This will also involve collaboration with the other review authors and re-formatting of the sections in line with the Cochrane style.

#### Results

## **Description of studies**

### Results of the search

See table 4 p.106

Table 4 Search details summary carried out by Anne Littlewood (Trials

#### Search Co-ordinator for the Cochrane Oral Health Group

Cochrane Review Title: Hypnosis for the alleviation of anxiety in patients undergoing dental treatment (0273) Contact Reviewer: Cath Potter

Summary of Searches

July 2012

Searches carried out by Anne Littlewood Trials Search Co-ordinator,

#### **Cochrane Oral Health Group**

Database	Version/issue	Date of search	<b>Records retrieved</b>
OHG Register	Whole database	23.07.12	84
CENTRAL via The Cochrane Library	To Issue 7, 2012	23.07.12	227
MEDLINE via OVID	1946 – 23 July 2012	23.07.12	101 (with filter)
EMBASE via OVID	1980 – 23 July 2012 (week 29)	23.07.12	73 (with filter)
CINAHL via EBSCO	1980 – 23 July 2012	23.07.12	198 (no filter)
AMED via OVID	1985 -23 July 2012	23.07.12	74 (no filter)
PsycINFO via OVID	1806 – 23 July 2012	23.07.12	14 (with filter)
ClinicalTrials.gov	Whole database	23.07.12	0
Meta Register of Controlled Trials	Whole database	23.07.12	5
Records de-duplicated and 549 records sent to Cath Potter, 24.07.12			

Saved Search strategies AL Ref:

OHG Register: 0273 Hypnosis for anxious adults 23.07.12 CENTRAL: 0273 Hypnosis.cochrane MEDLINE 0273 Hypnosis for anxious adults 23.07.12 EMBASE 0273 Hypnosis for anxious adults 23.07.12 CINAHL 0273 Hypnosis for anxious adults 23.07.12 AMED 0273 Hypnosis - anxious adults 23.07.12 PsycINFO Hypnosis for anxious adults 23.07.12 In addition, examination of reference lists of studies provided a further two studies.

Of the total of 551 references, examination of the abstracts provided 32 papers for which the full text was examined. For one reference (Wilson, 1996), the author was contacted for the full details of the study. Of these, 12 papers reporting 11 separate studies were included in the review whilst 20 were excluded. An additional paper (Mc Ammond et al., 1971) was identified from the reference list of an included study (Hammarstrand et al., 1995). Full text was obtained and the study was included in the review. One paper in German, was translated and the data extracted by Lisa Schell (Hermes et al., 2004). This was assessed as not fulfilling the requirement to be an RCT and was added to the list of excluded studies.

Tables of contents of The International Journal of Clinical and Experimental Hypnosis and Contemporary Hypnosis were searched for additional studies, but none were identified. It has not yet been possible to gain access to the full range of contents for the American Journal of Clinical and Experimental Hypnosis or the Australian Journal of Clinical and Experimental Hypnosis. Attempts to access these will continue for the full Cochrane Review. A total of 13 studies were therefore included in the review.

Summary details are given in the tables in the following sections of characteristics of included studies tables (5.6,7,8) and reasons for exclusion in excluded studies (table 9)

#### **Included** studies

#### **Characteristics of the trials**

Studies were reported from 1971 to 2011 from the following countries:

- USA (four studies) (Mc Ammond et al., 1971, Katcher et al., 1984, Ghoneim et al., 2000, Mackey, 2010)
- Germany (three studies) (Eitner et al., 2006b, Eitner et al., 2011, Wannemueller et al., 2011),
- Sweden (four studies) (Enqvist et al., 1995a, Enqvist et al., 1995b, Hammarstrand et al., 1995, Enqvist and Fischer, 1997)
- Denmark (one study, two papers with Moore (2002)) reporting follow-up data) (Moore et al., 1996, Moore et al., 2002)

None of the studies reported a sample size calculation.

#### **Characteristics of the participants**

All participants in the studies were adults, the largest age range in a single study being 19-80 (Eitner et al., 2011)

Ten studies contained a mixture of male and female participants, one included women only (Hammarstrand et al., 1995) and one study did not report the gender of participants (Katcher et al., 1984). In the remainder of the studies, nine contained more women than men (Mc Ammond et al., 1971, Enqvist et al., 1995b, Moore et al., 1996, Enqvist and Fischer, 1997, Ghoneim et al., 2000, Eitner et al., 2006b, Mackey, 2010, Eitner et al., 2011, Wannemueller et al., 2011)and one study more men than women (Enqvist 1995a). Patients with a wide range of anxiety levels were included in the studies with only a few studies involving highly anxious or phobic patients (Hammarstrand et al., 1995, Mc Ammond et al., 1971, Moore et al., 1996, Moore et al., 2002, Wannemueller et al., 2011). The remainder of the studies included patients undergoing surgical interventions such as implant placement (Eitner et al., 2011, Eitner et al., 2006b), third molar surgery (Enqvist and Fischer, 1997, Ghoneim et al., 2000, Mackey, 2010), extraction of teeth (Katcher et al., 1984) and oral/maxillofacial surgery (Enqvist et al., 1995a, Enqvist et al., 1995b).

In addition to variations in treatments, some studies investigated patients treated under general anaesthesia (GA) (Enqvist and Fischer, 1997, Enqvist et al., 1995a, Enqvist et al., 1995b), some using intravenous sedation (IV sedation) (Ghoneim et al., 2000, Mackey, 2010) and the rest treatment under local anaesthesia (LA) (Eitner et al., 2011, Eitner et al., 2006b, Hammarstrand et al., 1995, Mc Ammond et al., 1971, Moore et al., 1996, Moore et al., 2002, Wannemueller et al., 2011). Some of the studies involving treatment under LA used patients treated under GA as control

patients.

Table5 gives the characteristics and numbers of participants in included studies.

Study ID	Total n	Age (range or mean(SD)	Sex	Source of patients/setting of study	Other demographic details	Range of anxiety levels	Inclusion criteria	Exclusion criteria
1 Eitner et al (2006b)	45	Mean 38.8	27F/18M	Not specified	Anxious and non- anxious patients having implants placed	Normal range	Not given	Patients suffering from a pathological mental disease (10 exclusions)
2 Eitner et al (2011)	82	Mean 50.7 Range 19-80	56F/26M	Local dental office	Patients having implants placed under local anaesthesia (LA)	Normal range	Candidates for dental implants under LA	Cases requiring general anaesthesia (GA)
3 Enqvist and Fischer (1997)	72	Experimental group – mean 27.7(6.23) Control group 28.5(5.35)	36F/33M	Waiting list for oral surgery Sabbatsbergs Hospital or Sodersjukhuset. Not clear whether patients received LA, GA or sedation for surgery. (most probably GA as previous experience of anaesthesia is referred to in the paper.	Only patients with no previous experience of 3 <sup>rd</sup> molar removal	Normal range	Patients on waiting list (WL) for surgical removal of 3 <sup>rd</sup> molars	Patients with previous experience of 3 <sup>rd</sup> molar removal
4 Enqvist et. Al (1995a)	120	Control groups: A 22.6(9.4) B 23.4(11.4) C 24.3(12.2) Experimental groups: A 22.3(5.3) B 24.6(11.5) C 22.7(8.3)	38F/82M	Waiting list for bimaxillary orthognatic surgery Sabbatsbergs Hospital. All patients treated under GA	Experimental and control groups matched for complexity of surgery	Normal range	Control group patients matched for surgery	None reported

# Table 5 Characteristics of patients in included studies

Study ID	Total n	Age (range or mean(SD)	Sex	Source of patients/setting of study	Other demographic details	Range of anxiety levels	Inclusion criteria	Exclusion criteria
5 Ghoneim et al (2000)	60	Experimental group: 22.8(5.1) Control group: 23.6(2.3) Range 18-35	35F/25M	Patients scheduled for surgical removal of molar teeth in busy hospital setting		Normal range	Age - 18-35 ASA I or II	Neurological or psychiatric disease, current or history of drug abuse, current use of CNS active medications
6 Hammarstand et al (1995b)	22	31.8(9.3) Range 20-50	All F	Patients referred to Dental fear research and treatment clinic	More than half low socioeconomic class, 32% on psychiatric medication	Highly anxious/phobic	Female	None given
7 Katcher et al (1984)	42	Range 21-60	Not reported	Patients scheduled to have extractions under local anaesthesia only in a Dental school	Suburban location of facilities	Normal range	Age 21-60 having elective extraction with LA	Patients to have nitrous oxide or premedication
8 Mackey (2010)	91	Range 18-25	59%F	Patients undergoing surgical extraction of impacted 3 <sup>rd</sup> molar teeth with IV sedation at several outpatient dental facilities			English as first language Weight between 50 and 100kg	Previous hypnotic experience, major psychiatric disorders (DSM-IV). Patients taking medication affecting HR/BP. History of illicit drug use. Allergy to sulphites. Pre-existing painful medical condition.
9 Mc Ammond et al (1971)	27	18-50	22F/5M	Dental office	Volunteers responding to an advert. 120 screened, 27selected according to	Anxious individuals considering themselves frightened of the dental situation	Subjects showing a marked rise in skin conductance (SC) when given or attempted LA injection and in	

Study ID	Total n	Age (range or mean(SD)	Sex	Source of patients/setting of study	Other demographic details	Range of anxiety levels	Inclusion criteria	Exclusion criteria
					inclusion criteria		need of dental care	
10 Moore et al. (1996, 2002)	174	Range 18-65	94F/80M	Dental Phobia Research Centre	Most self referred	Extreme dental anxiety (DAS >15)(Corah, 1969)	DAS score >15, need for dental treatment, comparable numbers of men and women, ages 18-65	None given
11 Wannemueller (2011)	137	38.5(11.8)	90F/47M	Dental clinic of the Augusta Hospital Bochum	Many patients had co-morbid disorders	Dental phobia	Dental phobia according to DSM-IV criteria	Dental treatment in previous year, use of Anxiolytic medication
12 Enqvist and Von Konow (1995b)	90	Experimental group: 23.9(8.3 Control group 22.6(7)	54F/36M	Department of oral surgery Sabbatsbergs Hospital	From urban area in or near Stockholm	Normal range	Healthy individuals awaiting orhognatic surgery	

### **Characteristics of Interventions and control procedures**

### Hypnotic Procedures

A variety of types of hypnotic intervention were used in the studies, some were interventions delivered as tape recordings (Enqvist et al., 1995a, Enqvist et al., 1995b Enqvist and Fischer, 1997, Ghoneim et al., 2000, Mackey, 2010, Eitner et al., 2011) and some were live (Mc Ammond et al., 1971, Katcher et al., 1984, Hammarstrand et al., 1995, Eitner et al., 2006b), one study used both live sessions and tape recordings for practice between sessions (Moore et al., 1996, Moore et al., 2002) whilst one study compared tape recorded with live hypnosis (Wannemueller et al., 2011). Most studies did not test their participants' hypnotisability, those that did (Katcher et al., 1984, Enqvist et al., 1995a, Moore et al., 1996, Moore et al., 2002) found that individual scores did not affect treatment outcomes.

Details of the hypnotic interventions are given in table 6.

# Table 6 Characteristics of hypnotic interventions

Study and ID	Number and type of Hypnosis interventions	Description of intervention(s)	Description sufficient to allow replication	Integrity of intervention
Eitner et al (2006b) 1	2 Group B – hypnosis instruction session Group D – hypnosis instruction and hypnosis for implant surgery	No details given	No	Not assessable as no details given
Eitner et al (2011) 2	1 Hypnosis plus relaxing music played through speakers in a pillow attached to dental chair during implant surgery	Breathing techniques, dissociation suggestions, internal guard, mentally proceeding to restful place. Background music at 60 beats per minute aimed to slow and synchronise to patients heartbeat. Changes in hypnosis text synchronised to harmonious music changes	Yes	All provided on tape, so well standardised
Enqvist and Fischer (1997) 3	1 Daily use of 20 minute audio tape for the week before surgery	Relaxation induction, 'suggestions to find a safe place or state, suggestions to enhance what the body already knows regarding control of bleeding, coagulation and healing, instructions regarding how dissociation and direct suggestion can alleviate pain, instructions on how to choose a personal way to access the relaxed state by means of breath control, by calming words or pictures or by combinations of what the patient prefers, a training segment occurred after coming back from the trance state. The patient was asked to choose his or her "own model" and tr this for 120 seconds until soft music indicated that the patients could return to their usual state of mind.'(Enqvist and Fischer, 1997) p. 104	Yes	Patients who did not use the tape or only used it once were excluded
Enqvist et. Al (1995a) 4	3 Group A - pre-operative hypnotherapy recording listened to once or twice daily Group B – pre-operative hypnosis as above plus intra-operative therapeutic suggestions given during general anaesthesia (GA)	Pre-operative recording – 17 minute tape including an induction and direct and indirect suggestions and metaphor for improved healing, less bleeding, faster recovery, keep blood pressure low during the operation plus instructions on self-hypnosis and relaxation. Intra-operative suggestions similar plus assurance that surgery and anesthesia were well controlled during surgery (Enqvist et al., 1995a) p 287	Yes. Transcript of the tape available on request from the author	No control or recording of how many times patients listened to the tape before surgery

Study and ID	Number and type of Hypnosis interventions	Description of intervention(s)	Description sufficient to allow replication	Integrity of intervention
	Group C – intra-operative therapeutic suggestion only			
Ghoneim et al (2000) 5	1 Tape recorded hypnosis 1 day per week for 1 week before surgery	Tape was an English translation of that used in previous studies (Enqvist and Fischer, 1997, Enqvist et al., 1995b) Patients also had standard IV sedation, 50% nitrous oxide sedation and LA	Yes	All patients reported listening to the tape daily
Hammarstand et al (1995b) 6	1 Eight live sessions	Live sessions including progressive relaxation and comfort, visualisation of dental scenes concordant with the video scenes included in the control condition It was suggested that the patient 'would no longer be afraid of the imagined dental situation while maintaining relaxation' (Hammarstrand et al., 1995) p 400	Yes	As the sessions were live, standardisation would be difficult to achieve
Katcher et al (1984) 7	2 Poster contemplation with hypnosis and aquarium contemplation with hypnosis	Induction procedure and five suggestibility tests from the Stanford Hypnotic Susceptibility Scale (Wietzenhoffer and Hilgard, 1957). Subjects then contemplated the poster or aquarium for 10minutes and given posthypnotic suggestion that they could re-enter hypnosis during the dental procedure by closing their eyes and visualising the poster or aquarium	Yes	Intervention was scripted so could be standardised for all participants
Mackey (2010) 8	1 Standard IV sedation plus Propofol and Pre-recorded tape including hypnotic suggestion and relaxing music	No detail given except that intervention included rapid induction and therapeutic suggestion	No	Pre-recorded and therefore standard for all participants
Mc Ammond et al (1971) 9	1 Group sessions twice per week for 7 sessions	Sessions included eye fixation, visual imagery, progressive relaxation and repeated suggestions that 'they would no longer be afraid to have their dentistry done and that they would feel no discomfort in the dental situation' (Mc Ammond et al., 1971) p 236	No	Live group sessions would be difficult to standardise but all participants would have been treated the same
Moore et al. (1996, 2002) 10	1 Hypnosis training in the dental chair with audiotape for home practice. Number of sessions is	Erickson technique. Patients learned to restructure negative thoughts and imagery of dental anxiety as a wall for the patients to find out how to get t the other side. Dissociations for particularly stressful situations and age regression in cases of previous traumatic experiences. Home tape 12	No	Standardisation not possible

Study and ID	Number and type of Hypnosis interventions	Description of intervention(s)	Description sufficient to allow replication	Integrity of intervention
	unclear as training was considered complete when patients chose to go on to go on to treatment sessions (mean training time = 7.4h(4.9)	minutes plus second side of 5min self-induction for use at dental visits		
Wannemueller (2011) 11	2 Standardised hypnosis on CD listened to at home, 30mins before dental treatment and during dental treatment. Individual hypnosis CD about hypnosis given I week before treatment. Individual live hypnosis in dental chair 20mins before dental treatment and 10mins into treatment session	No details given of standardised hypnosis Individualised hypnosis – relaxation induction and imagery of previously explored pleasant imagery	No	Standardised hypnosis intervention same for whole group. Individualised hypnosis not standardised (not possible to standardise)
Enqvist and Von Konow (1995b) 12	1 Pre and peri-operative taped hypnosis. Pre-operative tape (18mins) listened to daily for 2 weeks before operation. Peri- operative tape listened to under GA during operation	Based on a cognitive behavioural approach including visualisation, transforming stress signals into relaxation and post hypnotic suggestions for minimal bleeding, low blood pressure and good rehabilitation. Self- hypnosis instruction and relaxation. Peri-operative tape also included reassurance about good control and safety during surgery	No but transcripts available on request from first author	Treatment standardised as tape recorded

## **Control Procedures**

Control procedures varied between studies. Most studies included a no anxiety treatment or waiting list control group. Some studies compared hypnosis to other forms of anxiety reduction, most often those involving anxious or phobic patients (Hammarstrand et al., 1995, Mc Ammond et al., 1971, Moore et al., 1996, Moore et al., 2002, Wannemueller et al., 2011).

Details given in table 7.

Study and ID	Number and type of Control groups	Description of contol intervention(s)	Description sufficient to allow replication	Integrity of intervention
1 Eitner et al (2006b)	3 Group A – no intervention Group C – surgery with no intervention	Group A – monitoring only Group C – monitoring and surgical intervention (implant insertion) only	Yes	Not applicable (N/A)
2 Eitner et al (2011)	1 Patients provided with same pillow but with no audio	No active intervention	Yes	Intervention to exclude any effects of having a special pillow attached to dental chair
3 Enqvist and Fischer (1997)	1 No intervention control	No intervention, surgery only	Yes	N/A
4 Enqvist et. Al (1995a)	3 No intervention control groups	Control groups had surgery only. Surgery was matched to patients in the intervention groups	Yes.	N/A
5 Ghoneim et al (2000)	1 No intervention control	Control groups had surgery only with standard IV sedation, 50% nitrous oxide sedation and LA	Yes	N/A
6 Hammarstand et al (1995b)	2 1.Eight live sessions of psychophysiological therapy 2.Patients treated under GA	Muscle relaxation, exposure to hierarchy of videotaped dental scenes with electromyographic (EMG) feedback. (Hammarstrand et al., 1995) p 400 GA patients had treatment under GA only	Yes	Video scenes were similar to scenes visualised in the hypnosis condition
7 Katcher et al (1984)	3 Poster contemplation without hypnosis and aquarium contemplation without hypnosis	Five suggestibility tests from the Stanford Hypnotic Susceptibility Scale (Wietzenhoffer and Hilgard, 1957). Subjects then contemplated the poster or aquarium for 10minutes and told they could relax during procedure by	Yes	Similar time and attention given to all groups

## Table 7 Control procedures in included studies

Study and ID	Number and type of Control groups	Description of contol intervention(s)	Description sufficient to allow replication	Integrity of intervention
	plus no intervention control	closing their eyes and imagining the poster or aquarium. Non intervention control patients seated in a chair for 40mins and told to relax.		
8 Mackey (2010)	1 Standard IV sedation plus Propofol and relaxing music	Music identical to that in hypnosis group	No	Pre-recorded and therefore standard for all participants
9 Mc Ammond et al (1971)	2 Relaxation training - group sessions twice per week for 7 sessions and listened to tape via headphones No intervention control	Tape 16mins long instructing participants in the technique of deep muscular relaxation. (Mc Ammond et al., 1971) p 236 No intervention control group given brief pain relief and relaxation instructions immediately before test procedures	Yes	Pre-recorded tape therefore standard No intervention considered inadequate so brief instructions given to second control group
10 Moore et al. (1996, 2002)	4 Systematic Desensitisation (SD) video and rehearsal, Group therapy (GT) and waiting list control (mean training time video SD = 9.2hrs (4.6), rehearsal SD = 5.8hrs(4.5) GT = 4.2hrs(0.9) WL control – no intervention, follow-up 3 years or more later	<ul> <li>Both SD groups had 12min progressive muscular relaxation (PMR) tape in the dental chair. Video SD – 8 videotaped dental situations with videos halted by therapist on request. Rehearsal SD direct simulated exposure to threatening dental situations or instruments combined with tension awareness training with hand signalled pauses and breath control.</li> <li>GT – 3 groups if 3men and 3women met for 7 x 2hr sessions led by therapist, dental assistant and former patient. Given information about phobic dental anxiety and social awareness training with relaxation training and video desensitisation as above. Final session demonstration of injection and drilling in clinic.</li> </ul>	Yes	Standardisation not possible

Study and ID	Number and type of Control groups	Description of contol intervention(s)	Description sufficient to allow replication	Integrity of intervention
11	2	CBT – psychoeducation on symptoms of anxiety, PMR with	Yes	CBT procedures given individually and
Wannemueller	Cognitive Behavioural Therapy	CD practice tape. Dysfunctional thoughts replaced by		these patients had more individual
(2011)	(CBT) – 2 sessions (60 & 50mins Treatment under GA	<ul><li>coping thoughts, fear hierarchy with imaginal scenes</li><li>followed by video scenes.</li><li>GA group had information about risks and informed consent</li><li>procedures and treatment under propofol GA</li></ul>		attention than the other groups
12 Enqvist	1	Control groups matched to intervention groups on surgery	N/A	N/A
and Von	No intervention control group	only and on sex and surgery		
Konow (1995b)	(surgery only under GA)			

### **Characteristics of outcome measures**

Outcome measures are described below with a summary table provided listing outcome measures used in each study (table 8).

### Self-report measures

Many self-report scales for anxiety, dental anxiety and general anxiety have been used in studies, but agreement between the scales is not always clear and this makes comparisons between studies difficult. This section will give an overview of the scales used in the included studies in this review. Many studies use more than one self-report measure.

#### Dental Anxiety Scale (DAS or Corah DAS)

This is a four item self-report scale developed to indicate the tendency for a person to be anxious about dental treatment or the dental situation (Corah, 1969, Corah et al., 1978b). It was the most common scale used in research in a review of measures between 1988 and 1998 (Newton and Buck, 2000). It has adequate reliability and validity (Corah et al., 1978b). The four questions relate to dental situations: having a dental appointment tomorrow, sitting in the waiting room, sitting in the dental chair waiting to have a tooth drilled and waiting to have your teeth cleaned. Each is scored 1-5 with 5 being the most anxious. Scores range from 4-20 with over 15 regarded as indicative of anxiety in the phobic range.

It was used as a screening tool or to compare groups at the start of treatment (Moore et al., 1996, Moore et al., 2002), as a tool to stratify samples for analysis (Eitner et al., 2006b), as a co-variant in analysis (Katcher et al., 1984) (this study states that participants filled in a dental anxiety scale, it is

likely that this was the DAS) and as an outcome measure comparing pre to post treatment (Hammarstrand et al., 1995, Wannemueller et al., 2011)

#### AZI

This is a German language measure designed to measure fear of dental treatment. It has six items designed to assess affective cognitive and somatic reactions with a visual analogue scale for each. The response range is continuous from "very much", through "quite a bit", "a little" to "not at all" giving a possible total from 0 to 60 with higher values representing more anxiety (Eitner et al., 2011).

#### **Dental Fear Survey (DFS)**

The DFS is a 28 item list which asks for responses to each item on a 5-point scale from 1- no reaction or fear to 5 – great fear or reaction. It includes items relating to avoidance, physiological arousal, fear of various aspects of the dental experience, fear amongst family and friends and an overall fear of dentistry rating. It has adequate internal consistency, reliability and validity (Kleinknecht et al., 1973, Kleinknecht et al., 1984). It was used as one of the primary outcome measures in one study (Moore et al., 1996, Moore et al., 2002).

### **Dental Beliefs Survey (DBS)**

The original DBS contains 15 items scored from 1 (highly positive beliefs) to 5 (highly negative beliefs) about the way that dentists behave in relation to their patients. It has been reported to have satisfactory validity and corrolates highly with the DFS (Kvale et al., 1997). Moore et al (1996,

2002) used this scale as one of the outcome measures in their study due to the ability of the scale to measure changes in trust towards dentists.

#### **Dental Cognitions Questionnaire (DCQ)**

This 38 item measure contains negative cognitions related to dental treatment, patients indicate whether or not they occur to them during dental treatment and the number indicated is summed to give a total score (de Jongh et al., 1995). This scale has been assessed for reliability and validity and shown to have good predictive validity, discriminant validity and reliability, although the authors suggest that more research is needed on this instrument (de Jongh et al., 1995). One study (Wannemueller et al., 2011) used the total scores on this scale as one outcome measure.

#### Visual Analogue Scales (VAS)

These can be used to measure any parameter and are designed as a continuous line (usually 10cm in length). The line is anchored at each end with descriptors designed by the experimenters. They have been used to measure anxiety (Eitner et al., 2006b, Enqvist and Fischer, 1997), sensations before and after treatment (Eitner et al., 2006b), well-being (Enqvist and Fischer, 1997), surgeon assessment of difficulty of treatment (Ghoneim et al., 2000), nausea and pain (Ghoneim et al., 2000), perceived degree of being afraid and expectation of being afraid of a new dentist (100 points maximum) (Moore et al., 1996, Moore et al., 2002) . Surgeon assessment of difficulty was also assessed using a numerical scale of 1-6 (Hammarstrand et al., 1995).

#### State Trait Anxiety Inventory (STAI)

This is a widely-used measure of anxiety which measures anxiety in general (20 items) (trait scale) and anxiety in specific situations (20 items) (state scale) (Spielberger, 1983). It consists of questions scored on a scale of 1-4 with higher values representing more anxiety. It has been tested and has good reliability and validity. The trait scale (STAI(T) is often used for pre-treatment screening and group comparisons (Moore et al., 1996, Moore et al., 2002) whilst the state scale (STAI(S) administered in a dental environment can be used as an outcome measure (pre-treatment compared to post-treatment (Ghoneim et al., 2000). One study considered both scales before and after treatment (Wannemueller et al., 2011)

#### Mood Adjective Check List (MACL)

A shortened form of this measure was used in one study, measuring two dimensions of mood, hedonic tone (unpleasantness–pleasantness) and degree of relaxation (calm-tense). It contained 23 randomly arranged adjectives describing either of the two mood dimensions. For each, the patient selected one of four responses from "definitely corresponds with how I feel" to "definitely does not correspond with how I feel". The scale is reported to have been tested on normal dental patients and psychology students in Sweden with mean scores of 2.8 (hedonic tone) and 2.7 (degree of relaxation) higher scores represent more desirable outcomes (Hammarstrand et al., 1995).

### Hierarchical Anxiety Questionnaire (HAQ)

This was used in one study and described as a rating of 11 hierarchically ordered phobic situations from 1-5. Cut off for dental phobia is given as 35 (Wannemueller et al., 2011) p 161.

### **Revised Iowa Dental Control Index (IDCI)**

A nine-item version of this scale was used as an outcome measure in one study (Wannemueller et al., 2011). This instrument measures desire for and perceived control during dental treatment. Those with a high desired control score and a low predicted control score showed higher dental fear and the scale was considered to have good reliability and validity (Brunsman et al., 2003).

### Geer Fear Scale (GFS)

Two studies used a modified form of the GFS (Hammarstrand et al., 1995, Moore et al., 1996, 2002). Moore et al (1996, 2002) used the scale for sample comparison. One study describes the scale used as a shortened form of the Fear Survey Schedule-II (Hammarstrand et al., 1995). 15 items from the original scale were used with 3 new ones. The specific situations are not given in the paper. It measures fears of 18 objects or situations known to produce phobic reactions. Each is scored 1-7 (not the least afraid to totally terrified).

#### The Dental Situation Reactions (DSR)

Used in one study (Hammarstrand et al., 1995), this describes 16 situations associated with dental treatment. Scoring is from 1-7 as above for the GFS.

#### Other Checklists and scoring scales

One study (Katcher et al., 1984) used a patient completed Treatment Comfort checklist (higher scores represent more comfort) and a dentist completed Patient Compliance Rating together with an observers rating. The first two measures are not described in the paper. The observer's rating was composed of recorded overt signs of anxiety or agitation. The number of entries per 5 minute period was used to derive a single score.

Another study used a 7-point patient rating scale asking "how successful has participation in this study been in alleviating your fears of the dental situation?" (Mc Ammond et al., 1971) p 237. This had responses ranging from "very successful" to "not successful at all". It is not stated in the paper which direction the scale followed.

One study used subjective ratings of treatment effectiveness and treatment dependence, participants rated how effective they considered their treatment had been (0-3, 0 - not at all, 3 - highly effective) and whether they would become distressed were the treatment not available  $(0-4 \ 0 - \text{not at all}, 4 - \text{highly distressed})$  (Wannemueller et al., 2011).

### Physiological measures

Physiological measures were used in many studies as an objective measure of stress or anxiety before, during or after treatment (or all of these time points).

Measures used were:

- EEG monitoring in which (alpha-) theta patterns were compared to beta patterns (Eitner et al., 2006b)
- Temperature (Eitner et al., 2006b)

- Salivary cortisol levels (Eitner et al., 2006b)
- Heart rate (HR) with increases suggesting increased levels of stress or anxiety (Eitner et al., 2006b, Eitner et al., 2011, Enqvist et al., 1995b, Katcher et al., 1984, Mackey, 2010, Enqvist et al., 1995a)
- Pulse oximetry measuring oxygen saturation (SpO2) (Eitner et al., 2011, Eitner et al., 2006b)
- Systolic (BPs) and diastolic blood (BPd) pressure with increased indicating increased stress or anxiety (Eitner et al., 2011, Eitner et al., 2006b, Enqvist et al., 1995a, Katcher et al., 1984, Mackey, 2010)
- Respiration rate (RR), slowing of respiration indicating reduced stress or anxiety (Eitner et al., 2006b)
- Skin conductance (SC) (Skin resistance (SR)) measured by polygraph with average SR results converted to SC in micromhos where lower values represent less stress (Mc Ammond et al., 1971)

### Acceptance of treatment

Some studies included whether their participants went on to accept dental treatment as part of the assessment of success of the intervention. These measures were taken at various times in different studies.

McAmmond et al (1971) followed up all their participants five months after the intervention, Moore et al (1996, 2002) followed up their patients at one year and three years following dental anxiety treatment.

### **Reduction in anxiolytic drugs**

Anxiolytic drugs were used in several studies, either as sedative drugs during treatment or as medications following treatment. The reduction in the amount of drug used was considered as part of the battery of outcome measures in some studies:

- Consumption of anxiolytic medications post operatively (Enqvist et al., 1995b, Enqvist et al., 1995a)
- Use of sedative agents intra operatively (Mackey, 2010)

Study ID	Measures Reported		
	Self-report	Physiological	Other and secondary measures
1 (Eitner et al., 2006b)	VAS anxiety (group D only)	EEG	
	VAS sensations (group D only)	Temperature	
	DAS (for group comparison only not outcome)	Salivary cortisol	
		HR	
		SpO2	
		BP	
		RR	
2 (Eitner et al., 2011)	AZI	BP	
		HR	
	TTA C	SpO2	
3 (Enqvist and Fischer, 1997)	VAS anxiety		
	VAS well being	DD	Destance of the second sector of the second s
4 (Enqvist et al., 1995a)		BPs	Post-operative consumption of anxiolytics
5 (Changing et al. 2000)	0T A 1/0\	HR	MAC
5 (Ghoneim et al., 2000)	STAI(S) DAS		VAS surgeon assessment Dentist's assessment
6 (Hammarstrand et al., 1995)	MACL P - (hedonic tone)		Completed/not completed study
	MACL C (degree of relaxation)		Completed/not completed study
	DSR		
	GFS		
7 (Katcher et al., 1984)	Patient treatment comfort index	BP	Observer rating
(Isatcher et al., 1904)	ratent treatment connort index	HR	Dentist rating

 Table 8 Summary of relevant baseline and outcome measures in included studies

Study ID	Measures Reported		
8 (Mackey, 2010)		BP and HR – these were kept stable by varying the amount of propofol sedation given so not really outcome measures.	Intra-operative propofol needed to stabilise sedation in mg
9 (Mc Ammond et al., 1971)	Patient rating of success in reducing anxiety STAI	SC	Dental attendance 5 months later
10 (Moore et al., 1996, Moore et al., 2002)	DAS – for sample comparisons only DFS DBS VAS (perceived degree of being afraid) VAS (expectation of being afraid of new dentist) STAI(T) – for sample comparison only GFS – for sample comparison only		Completion of anxiety treatment Hours of training needed Completion of dental treatment Long term follow-up regular dental treatment (3 years)
11 (Wannemueller et al., 2011)	DAS DCQ STAI IDCI		
12 (Enqvist et al., 1995b)		HR BP(s)	Post-operative consumption of anxiolytics

## **Excluded studies**

Twenty one papers reporting 19 studies were excluded from the study based on examination of the full text of the papers. The reasons for exclusion are given in table 9.

Table 9 Excluded studies - reasons for exclusion

Study	Reason for exclusion
(Abrahamsen et al., 2009)	Not anxiety or dental treatment
(Armitage and Reidy, 2012)	Not hypnosis
(Barber et al., 1979)	Not dental anxiety or hypnosis
(Becker, 2011)	Not hypnosis
(Berggren et al., 2000)	Not hypnosis
(Biggs et al., 2003)	Not hypnosis
(Bills, 1993)	Not RCT
(Corah et al., 1979a)	Not hypnosis
(Corah et al., 1979c)	Not hypnosis
(DiClementi et al., 2007)	Not patients
(Dyas, 2001)	Retrospective study not RCT
(Edmunds and Rosen, 1984)	Not hypnosis
(Hakeberg et al., 1997)	Not hypnosis
(Hermes et al., 2004)	Not an RCT
(Jerremalm et al., 1986)	Not Hypnosis
(Moore and Brodsgaard, 1994)	Not hypnosis
(Thom et al., 2000)	Not hypnosis
(Willumsen and Vassend, 2003,	Three papers reporting results of one study.
Willumsen et al., 2001b, Willumsen et al.,	Not hypnosis
2001a)	
(Wilson, 1996)	Report of a pilot study. Original unpublished dissertation obtained. Not randomised, no inter-group comparisons made.

## **Risk of bias in included studies**

All included studies were assessed for sources of bias according to chapter 8

of the Cochrane Handbook for Systematic Reviews of Interventions

(Higgins et al., 2011) including:

- Allocation (selection bias)
- Blinding (performance bias and detection bias)
- Incomplete outcome data (attrition bias)

- Selective reporting (reporting bias)
- Other potential sources of bias

Studies were allocated to low, unclear or high risk of bias according to the protocol for the review and according to the Cochrane Collaboration's tool for assessing risk of bias reproduced below (Higgins et al., 2011) p 9-10.

Table 8.5.a: The Cochrane Collabor	ation's tool for assessing risk of bias

Domain	Support for judgement	Review authors' judgement
Selection bias		
Random sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.
Performance bias		
Blinding of participants and personnel Assessments should be made for each main outcome (or class of outcomes).	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
Detection bias		
Blinding of outcome assessment Assessments should be made for each main outcome (or class of outcomes).	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.
Attrition bias		
Incomplete outcome data Assessments should be made for each main outcome (or class of outcomes).	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Attrition bias due to amount, nature or handling of incomplete outcome data.

Reporting bias		
Selective reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting.
Other bias		
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool.	Bias due to problems not covered elsewhere in the table.
	If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	

The majority of studies had at least one source of bias judged to be high and all studies included items assessed as having unclear risk of bias.

Random sequence generation and allocation concealment were generally not described in enough detail and therefore most often judged as unclear risk of bias. Some studies should only be characterised as quasi-randomised and assessed as at high risk of bias on these criteria. Mackey (Mackey, 2010) used alternate allocation, whilst Moore et al (Moore et al., 1996, Moore et al., 2002) only randomised some of the participants, whilst some groups were consecutively assigned patients from the waiting list and Wannemueller et al (Wannemueller et al., 2011) had a receptionist allocate patients according to the availability of the therapist and the GA group was made up of patients who chose this method.

Blinding of participants is not possible in trials of hypnosis as it is not possible to hypnotise someone without their knowledge. It is not known what effect this may have on study outcomes, so this has been recorded as an unclear risk of bias. Knowledge of hypnosis being used may affect control group participants due to the 'hold-back effect' which has been reported in experimental investigations of the effects of hypnosis (Braffman and Kirsch, 1999, Rainville, 2008), although this has been reported in crossover trials rather than in RCTs. This is described in more detail in chapter 4. Blinding of personnel and outcome assessors was also problematic as the experimenter or the dentist was also the hypnotist in many studies. One way to minimise this effect was to deliver the hypnotic intervention on tape although one study compared standardised hypnosis to live hypnosis and found an advantage to live hypnosis (Wannemueller et al., 2011). Studies involving dentally anxious patients generally had a high level of drop-outs, but these were clearly described and drop-out behaviour was considered part of the results of the studies in some cases. Selective reporting of results was not a large problem with most studies reporting all outcome measures described in their methods section.

Other sources of bias included differential attention from professionals in the hypnosis, comparison groups or control groups and financial issues. A single risk of bias table will be provided for each trial below tables 10-21.

## Table 10 Study 1 (Eitner et al., 2006b)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Method not stated. "20 randomly selected patients who had to undergo implant insertion" "another 28 randomly selected patients take as a control group" p459	Unclear
Allocation concealment	Method not reported	Unclear
Performance Bias		
Blinding of participants	No – not possible. The control group A had no intervention, group B had instructional hypnosis (session 2) but no surgery and group C had implant surgery without hypnosis (session 2)	Unclear
Blinding of personnel	Blinding of hypnotist not possible Blinding of surgeon not stated	Unclear
Detection Bias		
Blinding of outcome assessment	Not reported in the paper who assessed the outcomes or whether they were blinded. However, physiological parameters were measured appropriately and objectively using automated equipment.	Unclear
Attrition Bias	•••	
Incomplete outcome data	Three drop-outs reported in test group (D) This data not included in the analysis clearly recorded along with the anxiety levels – 1 anxious and 2 less anxious	Low
Reporting Bias		
Selective reporting	Not all outcomes are reported for all groups, but all relevant outcomes reported. Protocol not available for comparison	Unclear
Other Bias	•	
Other sources of bias	The hypnosis and control groups were received very different amounts of time and attention Group D had 3 sessions before surgery; 1 – monitoring, 2 - history taking and scale and polish, 3 - hypnosis instruction session. Comparison group C had only session 1 monitoring before their surgery without hypnosis.	High

## Table 11 Study 2 (Eitner et al., 2011)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Random numbers generated by computer software package then even numbers allocated to hypnosis, odd to control	Low
Allocation concealment Performance Bias	Practice management software used to assign patients	Low
Blinding of participants	Not possible although control group used the audio pillow without sound. It is unclear whether this would reduce bias	Unclear
Blinding of personnel	Not possible as the surgeon could hear the audio tape	Unclear
Detection Bias		
Blinding of outcome assessment	It is not clear from the paper who assessed the outcomes but physiological measures were carried out appropriately and objectively.	Unclear
Attrition Bias		
Incomplete outcome data	All participants completed the study	Low
Reporting bias		
Selective reporting	All outcomes reported	Low
Other Bias		
Other sources of bias	The length and complexity of surgery is not reported in the paper. If there was a difference in this between the groups, this could have affected outcomes	Unclear

# Table 12 Study 3 (Enqvist and Fischer, 1997)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Envelope method but insufficient detail given to assess further. Envelopes for the hypnosis group contained an audiotape and so may have looked or felt different than those for the control group	Unclear
Allocation concealment	Paper states that the surgeon and assisting personnel were not aware of patient group assignments.	Low
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Yes Patients were told not to reveal this information to surgeon or assisting personnel.	Low
Detection Bias		
Blinding of outcome assessment	Outcome assessors were the surgeon and the nurse who were blind to the group assignment	Low
Attrition Bias		
Incomplete outcome data	Three patients excluded from the intervention group. One did not complete the protocols, one listened to hypnosis tape once and one not at all. This could be a source of bias.	Unclear
Reporting bias		
Selective reporting	All outcomes are reported, although data is only presented for the significant findings. Other outcomes are reported as "No significant differences were found between the experimental and the control group on any of the other factors" p 105	Unclear
Other Bias		
Other sources of bias	The experimental group was more anxious than the control group at baseline	Unclear

## Table 13 Study 4 (Enqvist et al., 1995a)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Method of randomisation not stated. 60 patients were randomly assigned to the 3 experimental groups. Controls were 60 patients operated on at the same time who were matched for type of surgery to the 3 experimental groups	Unclear
Allocation concealment	Method not stated	Unclear
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	"Blood loss, HR and BP was monitored by staff not involved in or informed about the study" p.289.	
	Orthodontist – hypnotherapist was aware of the group allocations but was not present	
	during surgery and the hypnosis was delivered by tape recordings	
Detection Bias		
Blinding of outcome assessment Attrition Bias	Outcomes were all physiological measures, collected as above	Low
Incomplete outcome data	Three of the experimental group declined to be part of the study	Low
Reporting bias		
Selective reporting	Not all outcomes described in the methods section are reported	Unclear
Other Bias		
Other sources of bias	During surgery, the anesthetists were aware that tape recordings were being played in 2	Unclear
	of the experimental groups and not the control groups which could have influenced them.	
	Most of the experimental group had previous contact with the hypnotist/orthodontist so	
	"a desire to please may have been part of the positive response" p 289	

## Table 14 Study 5 (Ghoneim et al., 2000)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Patients allocated randomly, method not stated	Unclear
Allocation concealment	Not stated	Unclear
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Not stated whether the surgeon or other personnel were blinded, however, the abstract of the paper states that the trial was partially blinded.	Unclear
Detection Bias		
Blinding of outcome assessment	It is not stated whether the research assistant who administered the STAI was blind to the group allocation or who administered the same scale before surgery. It is not stated who monitored the patient during surgery or who measured the other variables.	Unclear
Attrition Bias		
Incomplete outcome data	All patients completed the study	Low
Reporting bias		
Selective reporting	All outcomes listed in the methods section are reported in results section but protocol not available	Low
Other Bias		
Other sources of bias	Patients in the control group did not have a control tape to listen to	Unclear

## Table 15 Study 6 (Hammarstrand et al., 1995)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Method not stated, paper reports that patients were randomly assigned to the two treatment groups. Control group was consecutively selected from the waiting list who received treatment under GA	Unclear
Allocation concealment	Not reported	Unclear
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Therapist – not possible to blind	Unclear
	Dentist providing treatment – not stated if they were blind	
Detection Bias		
Blinding of outcome assessment	It is not stated in the paper who administered the battery of self-report measures. It is not stated whether the dentist providing the dental treatment and providing the dentist's rating was blind	Unclear
Attrition Bias		
Incomplete outcome data	Eight patients dropped out before completion of fear therapy and one during dental treatment. Thirteen out of 22 patients, 8 PP group and 5 hypnotherapy patients completed the study. These are reported not to differ from those who completed the study	High
Reporting bias		
Selective reporting Other Bias	All measures described in the methods section are reported but protocol not available	Low
Other sources of bias	Appears to be free of other sources of bias	Low

## Table 16 Study 7 (Katcher et al., 1984)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Not reported – patients were randomly assigned	Unclear
Allocation concealment	Not reported	Unclear
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Dentist – blinded	Low
	Other personnel – not stated whether any present	
Detection Bias		
Blinding of outcome assessment	Observer who collected the self-report data, assessed overt signs of anxiety or agitation on a check-list and took the dentist rating was blind to the group allocation	Low
Attrition Bias		
Incomplete outcome data	All patients completed the study	Low
Reporting bias		
Selective reporting	All outcome measures described in methods section are reported in the results section but the results of the dental anxiety scale (used as a covariant in the analysis) are not reported	Unclear
Other Bias		
Other sources of bias	Length and complexity of dental treatment was not controlled for and the treating dentists varied in their approach to the patient	Unclear

## Table 17 Study 8 (Mackey, 2010)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Patients alternately assigned by an oral surgery assistant	High
Allocation concealment	Alternate assignment means that the allocation was not adequately concealed.	High
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Anaesthetist (researcher) blind	
	Oral surgeon blind	
Detection Bias		
Blinding of outcome assessment	Outcome is the amount of IV propofol needed to stabilise the vital signs (HR, BP) during surgery. These were monitored automatically so the amount of propofol administered is	Low
	determined objectively. In addition, the anaesthetist was blind to group allocation	
Attrition Bias		
Incomplete outcome data	All included participants completed the study	Low
Reporting bias		
Selective reporting	All outcome measures specified in the method section are reported in results	Low
Other Bias		
Other sources of bias	There is no 'no treatment' control group	Unclear
	No information is given about any variation in surgery type of length of procedure which may affect the amount of sedative drug used	

## Table 18 Study 9 (Mc Ammond et al., 1971)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Method not stated – subjects were randomly assigned	Unclear
Allocation concealment	Not reported	Unclear
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Dentist/hypnotist not possible	
Detection Bias		
Blinding of outcome assessment	Experimenter completed all the outcome assessments. It is not clear whether they were blind to group allocations.	Unclear
Attrition Bias		
Incomplete outcome data	One subject from the hypnosis group was excluded from the results due to equipment failure. It is not stated whether they differed from the rest at baseline or on other measures	Unclear
Reporting bias		
Selective reporting	All outcomes detailed in methods section reported in results	Low
Other Bias		
Other sources of bias	Relaxation training was carried out by use of tape recording and Ss were encouraged to use the tape between training sessions whilst the hypnosis training was delivered live with no practice between sessions	Unclear

## Table 19 Study 10 (Moore et al., 1996, Moore et al., 2002)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Hypnosis group consecutively assigned	High
	Systematic desensitization groups randomly assigned (2 groups –video and rehearsal)	
	Group therapy group consecutively assigned	
Allocation concealment	Waiting list control group Not described but consecutive assignment suggests not concealed	Iliah
Performance Bias	Not described but consecutive assignment suggests not conceated	High
Blinding of participants	Not possible	Unclear
Blinding of personnel	Therapist blinding not possible	Chereur
Detection Bias		
Blinding of outcome assessment	Not clear from papers who assessed outcomes	Unclear
Attrition Bias		
Incomplete outcome data	Whilst there were a large number of drop-outs during the study and at 3year follow-up	Low
	full details of these are given in the papers and used as part of the outcome measures	
Reporting bias		
Selective reporting	Outcomes outlined in methods section reported in results section	Low
Other Bias		
Other sources of bias	For the 3 year follow-up, different patients are included in the no treatment control group. Two different sets of patients are described, some of whom are followed up beyond 3 years. However, it is made clear in the paper which patients are included in which analysis.	Unclear

# Table 20 Study 11 (Wannemueller et al., 2011)

Domain	Support for judgement	Review author's judgement of risk of bias
Selection Bias		
Random sequence generation	Patients allocated by receptionist according to availability of the therapist. GA on demand of patient.	High
Allocation concealment Performance Bias	Not reported	Unclear
Blinding of participants	Not possible	Unclear
Blinding of personnel	Therapists – not possible Dentist – not reported	Unclear
Detection Bias	•	
Blinding of outcome	Paper does not state who collected the data. It is likely that it was collected by the therapists and the	High
assessment	dentists providing treatment as the paper states that data were missing "due to day-to-day clinical management problems" p 161	
Attrition Bias		
Incomplete outcome data	Drop-outs are clearly described in the paper and an intent to treat analysis was carried out on the main outcome measure. More drop-outs in standardised hypnosis group than other groups. Many participants had missing data and could not be included in the analysis, this is in addition to drop-outs	High
Reporting bias		
Selective reporting	All outcomes detailed in the methods section are reported in results section. However, M2 time-point is not reported for any group.	Unclear
Other Bias		
Other sources of bias	A contribution of 50 Euros was charged for the standardised hypnosis treatment. Other treatments were free of charge	High
	There was differential attention from professionals between the groups. CBT group had much more time than the other groups.	

# Table 21 Study 12 (Enqvist et al., 1995b)

Domain	Support for judgement	<i>Review author's judgement of risk of bias</i>
Selection Bias		
Random sequence generation	Paper states "patients were paired with regard to surgery and patients unknown to the orthodontist-hypnotherapist were prioritized into the experimental group. Remaining patients were randomized into control on experimental patients respectively" p 230-231. This was done to minimise the effect of "the wish to please" effect in patients who had previous contact with the hypnotherapist.	Unclear
Allocation concealment	Not stated	Unclear
Performance Bias		
Blinding of participants	Not possible	Unclear
Blinding of personnel	Not stated	Unclear
Detection Bias		
Blinding of outcome assessment	Staff recording the data during surgery did not know about the study.	Low
Attrition Bias		
Incomplete outcome data	No drop-outs from the study	Low
Reporting bias		
Selective reporting	All outcomes reported in methods section reported in results	Low
Other Bias		
Other sources of bias	Study appears to be free of other forms of bias	Low

### **Effects of interventions**

This review contains a varied set of studies. There are differences in the types of participants, types of hypnotic interventions, types of control and comparison procedures, dental procedures, with or without sedation or GA and outcome measures. Summaries of the methods, main outcomes (results), limitations and main conclusions of the study authors are described below. Studies involving patients with the full range of anxiety levels having oral surgery interventions will be presented first, followed by studies involving highly anxious or phobic individuals.

#### Studies involving patients with normal ranges of dental anxiety levels

#### Study 1 (Eitner et al., 2006b)

This study compares patients undergoing implant surgery and aims to test medical hypnosis as an appropriate intervention in anxious patients. Four groups described below with sessions at which monitoring took place: Group A (n=13) monitoring only Group B (n=7) monitoring, hypnosis instruction no surgery Group C (n=8) monitoring, surgery

Group D (n=17) split between high anxiety (DAS<13 n=8) and low anxiety (DAS>12 n=9) monitoring, examination and scale and polish, hypnosis

instruction, surgery with hypnosis, suture removal scaling or temporary prosthodontic rehabilitation by unknown dentist.

Relevant comparisons were between group C and group D at the surgery session (session 2 for group C session 4 for group D). Results relate to changes in the vital parameters of the patients between the initial to middle (IM) and initial to final (IF). Other results were reported for group D only to contrast low and high anxiety participants and are reported under other results.

Parameter measured	-	Group C	Group D high anxiety	Group D low anxiety	Reported significance
<b>Respiration rate</b>	IM	+3.1	-2.9	-0.4	p=.0003
(breaths per	IF	+1.6	-2.1	0	
minute					
BPs	IM	+5.8	-14.5	-8.9	p=.0003
	IF	-0.3	-8.9	-4.3	
HR	IM	-1.3	-6.4	-5.7	
	IF	-8.3	-3.3	-2.7	
BPd	IM	+4	-0.8	-2.5	
	IF	+0.9	-6.5	-2.3	
Salivary cortisol		Inconsistent – slight increase	Inconsistent – unc	hanged	
EEG		Beta activity	(alpha-) theta activ posterior section of with shifting of lat	Ŭ	Significant differences
Temperature and SpO2		Unchanged	Unchanged	Unchanged	

 Table 22 Summary of results table for (Eitner et al., 2006b)

#### **Other results**

The VAS (anxiety) was assessed for anxious and non-anxious patients and

showed a 5-point difference between anxious and non-anxious patients

(measured by the DAS).

VAS for sensations on the day of treatment under hypnosis and immediately

after surgery (0=very bad 10=very good) less anxious patients scored mean 5.9

and 6.2, more anxious patients scored mean 4.6 to 6.8.

100% of patients in group D indicated their interest in alternative healing methods like hypnosis

#### Main conclusions of study authors

Hypnosis reduces the stress profile on the day of surgery significantly. Relaxation increased and neurophysiologic anxiety reactions (vital parameters) decreased at the same time. As a long term treatment concept medical hypnosis gains the patient's confidence and his or her fear is reduced, which is reflected in the vital parameters.

#### Study 2 (Eitner et al., 2011)

This study compares patients having implant surgery under local anaesthesia.

The study was composed of two groups:

Hypnosis group (n=44) implant surgery under LA with music and hypnosis

played through an audio pillow

Control group (n=38) implant surgery under LA with same pillow but without music and hypnosis

Outcome measure	When measured	Hypnosis n=44	Control n=38	Reported significance
AZI	Before surgery	29.23+/- 9.83	29.58+/- 7.94	
	After surgery	15.29+/- 7.59	30.18+/- 7.42	
	Difference	-13.94(7.36)	0.6(7.36)	p=.00014
BPs	Difference before and during	+4.11%	+11.41%	NS
	Difference during and after	-2.72%	-5.48%	NS
BPd	Difference before and during	-7.79%	+7.44%	p=.045
	Difference during and after	-0.99%	-3.98%	NS
HR	Difference before and during	-4.74%	+9.71%	p=.024
	Difference during and after	-4.67%	-2.17%	NS
SpO2		No differences		

#### Table 23 Main results for (Eitner et al., 2011)

#### **Other results**

At the end of treatment groups were asked "would you undergo another implantation?" was 7.9 in hypnotherapy group and 6.4 in the control group.

#### Main conclusions of the Study authors

The music pillow with hypno-relaxation had anxiolytic effects. Objective and subjective parameters indicate anxiolysis is due to the trance state. Further studies are warranted.

#### Study 3 (Enqvist and Fischer, 1997)

The study compared patients having surgery for the surgical removal of 3<sup>rd</sup> molar teeth. It is not stated what method of anaesthesia was used, but it is likely that it was GA. The two groups were:

Hypnosis group – daily use of 20 minute hypnosis tape during week before

surgery (removal of 3<sup>rd</sup> molar, possibly under GA)

Control group – surgery only (as above), no other intervention

Anxiety measured 3 weeks before surgery and on the day of surgery.

#### Main results

Well-being measured from evening of day of surgery to 5 days after. These results are not reported in the paper.

#### Table 24 main results (Enqvist and Fischer, 1997)

	Hypnosis n=33	Control n=36
VAS anxiety at examination	5	2
VAS anxiety before surgery	4.4	4.9
Significance of change	NS	p=.002

#### **Other results**

Patients listened to the audiotape at least 3 times (median=5.5). Mean appreciation of the tape was 9.1 and mean effectiveness evaluation was 6.2 (out of 10 - 10 good). This was measured at the end of the study (day 5). The primary outcome in this study was pain and consumption of analgesics following the operation. Consumption of analgesics showed an advantage for hypnosis.

#### Main conclusions of the study authors

The experimental group maintained their pre-operative anxiety level on the day of surgery whereas anxiety increased in the control group. The hypnosis group was significantly more anxious at the start which is difficult to explain since patients were randomised and first anxiety measurement was done before group allocation.

#### Study 4 (Enqvist et al., 1995a)

This study compared patients having oral surgery procedures such as osteotomy under GA. There were three intervention groups, each with a control group matched for surgery. The authors note that groups A, B and C cannot be directly compared as the surgery was different between the groups. All groups had surgery under GA.

Group A n= 18 – Pre-operative 17minute hypnotherapy tape listened to once or twice daily given two weeks before surgery

Group B n=18 – pre-operative tape (as above) plus similar tape played

continuously during surgery under GA

Group C n=24 – peri-operative tape (as above) only

Relevant measures and times reported are: mean systolic BP (BPs) during surgery; heart rate (HR) measured post operatively and post-operative consumption of anxiolytics in the post-operative period. Other outcomes such as blood loss and consumption of analgesics are not considered relevant to this review.

#### Table 25 relevant results (Enqvist et al., 1995a)

Outcome measure	Group A		Group B		Group C	
	Control	Hypnosis	Control	Hypnosis	Control	Hypnosis
	n=18	N=18	n=18	n=18	n=24	n=24
BPs	104.7(8.4)	100.4(9.8)	101.9(8.3)	96.3(6.7)	103(7.8)	94.8(9)
Significance level	p=.165		p=.032		p=.002	
HR	81.4(12.9)	77.7(9.6)	83.6(17.6)	76.2(15.8)	81.8(16)	75(11.1)
Significance level	p=.312		p=.191		p=.98	
Consumption of	1.3(1.3)	0.6(1.1)	1.9(1.9)	1.63(1.6)	1.6(1.9)	1.8(2.2)
anxiolytics						
Significance level	p=.083		p=.622		p=.7	

#### **Other results**

Most of the patients listened to the preoperative tape ten times or more and 90% of the patients said that their well-being was increased by the preoperative tape.

#### Main conclusions of the study authors

Preoperative hypnosis is associated with lower blood loss. Perioperative blood pressure was lower when pre and perioperative hypnosis and suggestion were combined. For many patients the most important gain was the calmness they experienced before surgery.

#### Study 5 (Ghoneim et al., 2000)

This study was composed of two groups who both received surgical removal of molar teeth under sedation with Fentanyl, Midazolam at 0.1 mg/kg and 50% nitrous oxide in oxygen. They also received local anaesthesia lidocaine 2% with epinephrine 1:100,000.

Hypnosis group n=30 were given a hypnosis tape to use every day for one week before surgery.

Control group n=30 had surgery but no tape.

Relevant outcomes reported were STAI(S) measured at screening, pre-

operatively and immediately post-operatively and the changes compared. The

surgeon's assessment of the difficulty of the surgical extraction of each tooth

was measured on the day of surgery and a maximum and average value

calculated.

Number of vomiting episodes on the day of surgery and for the following 3 days were calculated.

Outcome measure	Control n=30	Hypnosis n=30	Significance level
STAI(s)mean change from	11.7(7.2)	5.5(13.9)	T test p=.03, Man
screening to post-op			Whitney U test p=.01
STAI(s) changes from pre-			NS
op to immediate post op			
Surgeon assessment (max	4.7(22.1)	35.8(22.9)	p=.18 NS
VAS)			
Surgeon assessment	31.1(17.8)	36.3(18.3)	p=.28 NS
(average VAS)			
Side effects mean number	0.27(1.05)	1.28(1.2)	p=.006
of vomiting episodes			

#### Key conclusions of study authors

Listening to an audio-tape with hypnotic instructions for one week before molar teeth extractions results in reduced anxiety before surgery. The increase in incidence of vomiting in the hypnosis group was unexpected and difficult to explain.

#### Study 7 (Katcher et al., 1984)

This study was composed of four intervention groups and a no intervention control. All groups had the extraction of teeth under LA, but the surgery varied in complexity and duration and was not matched between the groups.

The outcome measures were the patient treatment index and a dentist's patient compliance rating taken immediately after surgery an observer's rating (mean number of recorded overt signs of agitation/anxiety per 5minute period during surgery and BP and HR changes from initial reading and maximum reading after LA before completion of extractions.

The groups were:

Group 1 n=8 - Aquarium contemplation

Group 2 n=8 – Poster contemplation

- Group 3 n=8 Poster contemplation with hypnosis
- Group 4 n=8 Aquarium contemplation with hypnosis

Group 5 n=10 - No intervention control

#### Tables 27 and 28 reported results of (Katcher et al., 1984)

	Group 1 n=8	Group 2 n=8	Group 3 n=8	Group 4 n=8	Group 5 n=10
Mean (standard error) for patient comfort index	40.3(3)	26.5(3.1)	37.7(3)	38.3(3)	29.9(2.7)
Significant differences	-	p<.001, group p 3&5 p<.05 g			1,group 2&4

2-Way Analysis of			p value
Variance			
Patient comfort			
index			
	Aquarium	No aquarium	
	40.3	31	.009
	Hypnosis	No hypnosis	
	38.5	32.5	.02
	Interaction		.003
<b>Observer's rating</b>			
Ũ	Aquarium	No Aquarium	
	1.2	3.9	.06
	Hypnosis	No hypnosis	
	1.3	3.8	.05
	Interaction		.1
Dentist's rating			
8	Aquarium	No aquarium	
	42.2	36.8	.11
	Hypnosis	No hypnosis	
	41.8	37.2	.13
	Interaction		.04

All of the above results were done corrected for the dental anxiety index. The

authors do not give the scores on this measure.

#### **Other results**

HR and BP did not vary between the groups and the four test groups did not

vary in the average number of suggestions accepted on the tests of

suggestibility.

#### Main conclusions of study authors

Contemplation of an aquarium before oral surgery can alter subjective experiences and overt behaviour. Hypnosis significantly increased the effectiveness of contemplating a poster, but not the effectiveness of aquarium contemplation.

#### Study 8 (Mackey, 2010)

This study compared intra-operative music and hypnosis to intra-operative music only for patients undergoing surgical extraction of impacted 3<sup>rd</sup> molars under intravenous sedation. All patients received 50mcg Fentanyl, 3mg Midazolam 100mg propofol and 8mg Decadron IV. The main relevant outcome measure was the dose of propofol given to stabilise vital signs measured at 5minute intervals throughout the procedure. The numbers in each group are unclear in the paper. A total sample size of 91 is reported, but the abstract gives figures of 46 in the hypnosis group and 54 in the control group.

#### Table 29 Relevant reported outcomes (Mackey, 2010)

	Hypnosis group	Control group	Significance level MANOVA	Significance level ANOVA
Intraoperative	117.85(42.51)	154.08(50.86)	p<.001	p<.01
propofol mean(SD)				

#### **Other results**

Other measures were postoperative pain and postoperative consumption of

analgesics which are not relevant to this review.

#### Main conclusions of study authors

The addition of hypnotic and therapeutic suggestions throughout the entire surgical procedure helps reduce the amounts of intra-operative anaesthetics needed to stabilise vital parameters decreasing associated risks and costs. Further research is needed on a larger scale with the addition of a no treatment control group.

#### Study 12 (Enqvist et al., 1995b)

This study evaluated the use of a hypnosis tape used daily for two weeks before and during orthognatic surgery under GA. The control group had no tape recordings. Outcome measures relevant to this review were the mean HR and BPs measured every 15minutes during surgery, mean post-operative HR measured for 12 hours after surgery and postoperative consumption of anxiolytic medication postoperatively. It is similar to study 4 (Enqvist et al., 1995a) and the author states that it is less susceptible to bias as patients that he had previous contact with are more equally allocated to experimental and control groups. Analysis was done in two ways, with the groups matched for sex and surgery (19pairs) and with groups matched for surgery only (45pairs).

Tables 30 and 31 Relevant outcomes of the study (Enqvist et al., 1995b)

1 5 85			
Outcome	Experimental group	Control group	p-value
BP mmHg during operation	95(8.5)	94.4(13.4)	.075
HR mean during surgery	69.4(9.6)	74.5(13.8)	.13
HR mean for 12hrs after surgery	68.9(12.7)	75(17)	.21
Anxiolytics post-op	0.42(.69)	0.95(1.4)	.003

Groups matched for surgery only

Outcome	Experimental group	Control group	p-value
BP mmHg during operation	93.9(8.9)	94.7(10.01)	.839
HR mean during surgery	76.7(10.7)	73.9(12.3)	.249
HR mean for 12hrs after surgery	70.8(13.5)	77.9(16)	.024
Anxiolytics post-op	0.56(.84)	0.72(1.11)	.44

#### **Other results**

Other results were that 95% of patients were positive towards the tape and 90% listened six times or more. Significant differences were also found between the groups on postoperative oedema and pyrexia which the authors suggest may be due to less stress in the hypnosis group.

#### Key conclusions of the study authors

The hypothesis that the effect of preoperative suggestion could be increased by suggestions in GA was not confirmed. The use of a hypnosis tape is cheap and simple and can be used in future stressful situations. More research is necessary.

## Studies involving highly anxious or phobic patients only

#### Study 6 (Hammarstrand et al., 1995)

This study compares women phobic dental patients who had hypnotherapy (HT) or psychophysiological therapy (PP) before dental treatment. The groups are further compared to patients who had treatment under GA. There were a number of drop-outs from the treatment groups – two PP patients and 6HT patients before completion of therapy sessions and one PP patient during the test dental treatment. Dental test treatments for both therapy groups were scaling, restoration of an upper premolar or molar under LA and restoration of an upper incisor under LA. Patients who completed these received a dentist's assessment and, if suitable were referred to another dentist to complete treatment. Outcome measures were taken at baseline then at each visit to the clinic. Changes from pre to post treatment were analysed.

Group	Outcome measure	Before treatment median	After treatment median	P value (Wilcoxon signed ranks test
	DAS			
PP n=8		16	8.5	.01
HT n=5		20	7	.06 NS
GA		16	11	.004
n=11				
	MACL P			
PP		1.6	3.1	.01
HT		1.4	3.8	.06 NS
	MACL C			
PP		2.0	3.0	.01
HT		1.5	3.3	.06 NS
	DSR			
PP		76	38	.02
HT		96	30	.11 NS
	GFS			
PP		48	43	.11 NS
HT		37	35	.27 NS
GA		47	49	.8 NS

Table 32 main reported results (Hammarstrand et al., 1995)

#### **Other results**

Dentist's ratings showed all but one patient PP group could be referred to another dentist to complete treatment.

#### Key conclusions of study authors

It is not possible to draw extensive conclusions from the study as it is a very small sample. Similar results were obtained for both treatments, although the results in the HT group failed to reach statistical significance. There is no clear reason why more HT patients dropped out than PP patients. A majority of the patients who completed the therapy and initial dental treatments became less anxious about dental care and all but one could manage conventional treatment.

#### Study 9 (Mc Ammond et al., 1971)

This study compared volunteers anxious about dental treatment who had a marked rise in skin conductance in a dental situation (attempted LA injection). The physiological outcome measure (SC) was taken at baseline and continuously at the test appointment. The self-report measures, STAI, patient rating of how successful participation in the study was to alleviate fears of the dental situation were completed after the test procedures. Five months later patients were contacted to find out if they had visited a dentist. There were 3 groups, relaxation training (n=9), hypnosis (n=8) and a no

intervention control group (n=10). The relevant test treatment was a local anaesthetic injection.

#### Relevant results (Mc Ammond et al., 1971)

SC results were stratified in each group according to baseline level high medium and low. Baseline SC levels and SC levels at the injection were compared using an ANOVA. Raw scores and means are not given in the paper. The results showed that for participants with high baseline levels, hypnosis was significantly more effective than control, relaxation was less effective than hypnosis or control for those with medium baselines and there were no differences for low baseline participants.

STAI data showed no differences between the groups and scores were unrelated to SC levels.

Rating of success of treatment showed that all groups differed from one another hypnosis rated most effective and control least (p<.05).

At 5 month follow-up, significantly more participants in the hypnosis group 8/8 than the relaxation group 1/9 had dental work done. Other comparisons showed that hypnosis = control 5/10 and relaxation = control.

#### Main conclusions of study authors

Skin conductance is complex and difficult to interpret. The physiological measures seem to be unrelated to the self-report and behavioural measures. The most important result is future approach behaviour. Hypnosis was the most effective in this regard.

#### Study 10 (Moore et al., 1996, Moore et al., 2002)

Two papers describe this study comparing several interventions aimed to reduce anxiety and promote regular dental attendance in highly anxious patients.

The comparison groups were:

- two forms of systematic desensitisation (video SD and rehearsal SD)
- group therapy
- hypnosis
- an untreated waiting list control group.

The patients were followed up three years later to assess the outcome measures and regularity of attendance (Moore et al., 2002).

Self-report outcome measures (DFS and DBS) were taken at T1 (prior to first appointment), T2 (after patients decided to go on to test dental treatment) T3 (after test dental treatments), T4 (1year later) and at 3 year follow-up. For the waiting list control patients, T1 was at initial registration and T2 6 months later. A 100 point VAS for anxiety was completed at the same times for the intervention groups. A similar VAS was taken for the expected anxiety regarding going on to an outside dentist for continuation of treatment (Tex) at T3. Drop-out behaviour was continuously monitored and dental attendance was assessed at one and three year follow-up. Summary tables (tables 22-35) and descriptions of results are given below.

#### Relevant results (Moore et al., 1996, Moore et al., 2002)

Table 33 Drop-out behaviour and regular dental attendance at 3yrs in the testgroups and 3yr reference control group

Group	N start	N drop outs during training	N did not go on to test treatment	N went on to treatment 1year	N went on to regular treatment 3year	N not contactable at 3year
Video SD	32	5		3	19	1
Rehearsal	34	1	4	29	17	4
SD						
Group	30	6	9	15	16	1
Therapy						
Hypnosis	25	3	10	12	12	
3year	51 (in				7	
control	original					
group	study)					
	18 (in					
	follow-up)					

Significant group differences were only reported between the 12 HT group

patients and the 53 combined SD patients in going on to seek treatment with an outside dentist (p=.004). Video SD patients were the only group to be

significantly more likely to go on to become regular attenders than the 3 year reference control group p=.005.

Table 34 main outcome measures for anxiety and trust (T1-T4 show values from original paper (Moore et al., 1996)3 year change values from follow-up study (Moore et al., 2002)

Time point	Video SD mean(SD)	Rehearsal SD mean(SD)	Group Therapy mean(SD)	Hypnosis mean(SD)	Control (mean(SD)
DFS					
T1	76(12.8)	73(13.3)	78.4(10.3)	81.5(12.5)	80(10.7)
T2	39.5(12.8)	37.8(10.5)	36.5(10.3	38.1(14.9)	76.3(15.6)
Т3	30.1(7.2)	33.3(8.1)	27(6.4)	29.7(9)	
T4	34.9(100	42.9(12)	29.6(8)	40.6(23.5)	subgroup at 3years
3year follow-up (regular attenders) DBS	38.3(16.1)	42(13.6)	31.6(8.3)	33.8(19.6)	66.3(16.7)
T1	46.6(13.6)	46.6(9.9)	46.6(11.5)	48.3(13.5)	50.2(13.8)
T2	20(9.4)	18.8(3.9)	18.7(6.5)	20(9.3)	46.9(16.2)
T3	16.8(3.8)	18(3.9)	16.2(2.2)	16.3(2.8)	,
T4	19.5(8.9)	24.4(12)	19.1(5.8)	22.8(12.3)	subgroup at 3years
3year follow-up (regular attenders) VAS (anxiety)	21.8(9.7)	19.5(6.7)	19(5.3)	21.3(10.1)	26.9(16.7)
(anxiety)	86.7(12.3)	88.2(8.4)	88.8(11.4)	91.8(8.8)	
T3	14.8(12.8)	15.2(13.9)	8.3(10.5)	11.8(12.2)	
13 T4	16.5(13.8)	32.1(22.5)	10(10.4)	26.4(30.4)	
VAS (Tex) at T3	25.4(15.6)	34.8(20)	23.3(19.9)	30.9(22.5)	

VAS scores decreased significantly for all groups after the test treatments

p<.001 with a significant increase about facing a new dentist (Tex) p<.001 with no differences between the groups.

Between T3 and T4 DFS showed significant increases in anxiety for all groups (HT p=.053, GT p=.05, video SD p=.02, rehearsal SD p<.001). Decreased trust

(DBS score) was only significantly different in rehearsal SD p<.001, although trust scores reduced in all groups reflecting increased trust.

Significant within group improvements for regular attenders in all intervention groups for DFS and DBS were found between T1 and 3year follow-up p<.001, whereas the control group showed significant changes for DFS only p=.002. Changes in DFS scores were significantly lower in the rehearsal SD group than in other intervention groups p<.03.

#### **Other results**

Number of hours training needed before going on to test dental treatments was calculated and GT patients needed the least time. HT group needed longer than direct rehearsal SD (p=.054) but not video SD.

The amount of trust increase for the HT group from T1 to T3 was negatively correlated with the required number of training hours in those who went on to further treatment with an outside dentist.

#### Key conclusions of the study authors

All methods were effective in dental anxiety reduction and improved trust between T1 and T3. The HT and GT groups had the greatest attrition. Hypnosis appears to make the patient feel more dependent on a specific therapist. Hypnosis may be an important treatment method for some odontophobic individuals (Moore et al., 1996).

Overall, intervention patients were significantly better dental care attenders after 3years than reference controls. All intervention 3year regular attenders were significantly less anxious and had more positive beliefs about dentists than for the whole control group. It could be concluded that many anxious patients can successfully start and maintain regular dental treatment on their own (Moore et al., 2002).

#### Study 11 (Wannemueller et al., 2011)

This study compared four groups of highly anxious patients who received three interventions aimed to reduce anxiety to each other and to patients who had treatment under GA. Outcome measures were taken at M1 - at the beginning of the trial, M2 - before the first dental treatment (not reported in the paper), M3 -the day after the first dental treatment and M4 - before the second dental treatment a week later.

The groups were:

- Cognitive Behavioural Treatment (CBT) n=19
- Standardised Hypnosis (SH) n=15
- Individual Hypnosis (IH) n=14
- General Anaesthesia (GA) n=29

#### Table 35 Relevant results (Wannemueller et al., 2011)

Measure and time-point	CBT	SH	IH	GA
DAS				
M1	17.03(2.58)	17.68(2)	18(2.48)	16.75(2.73)
M3	12.29	14.01	14.4	16.44
M4	12.61	14.56	13.76	16.26
Missing values	4	1	0	12
DCQ				
M1	16.27(4.96)	24.57(5.89)	21.54(8.68)	22.76(7.09)
M3	10.22	14.86	11.99	18.71
M4	10.14	17.68	9.79	16.77
Missing values	4	1	1	12
ICDI (desired				
control)				
M1	21.02(4.15)	22.33(2.31)	21.08(3.38)	19.69(3.9)

Measure and	CBT	SH	IH	GA
time-point				
M3	19.9	20.73	17.81	20.29
M4	19.72	20.7	18.12	19.63
Missing values	8	3	1	16
ICDI				
(perceived				
control				
M1	7.55 (92.34)	7.15(2.73)	7.54(3.17)	7.33(2.37)
M3	12.34	11.1	11.2	9.29
M4	12.42	10.27	11.1	9.22
Missing values	8	2	1	17
STAI(s)				
M1	44.3	59.25(9.04)	59.31(11.32)	62.18(10.88)
M3	42	31.91	44.08	49.55
M4	51.97	59.25	54.46	48.77
Missing values	9	3	1	18
STAI(t)				
M1	39.8(9.32)	43(9.51)	37.55(8.15)	48.33(11.06)
M3	38.7	41.1	41.39	39.03
M4	37.61	39.68	39.39	39.23
Missing values	9	2	3	17
Efficacy rating	2.31(0.48)	1.27(0.9)	2.11(1.05)	2.2(0.79)
(M4?)				
Missing values	6	4	5	19
Treatment	1.31(1.03)	1.44	2.22(1.3)	2.8(0.92)
dependence				
(M4)				
Missing values	6	4	5	19

Improvements in DAS scores were significant over time for all groups (p<.01),

CBT was more effective than GA with the other two groups in between. The number of patients who were still anxious (DAS cut off 13) at M3 differed between groups (p<.005) with ratios of anxious versus non anxious patients being 6:11 CBT, 12:3 SH, 8:6 IH and 14:6 GA. CBT was significantly more effective than SH (p<.003) and GA (p<.02). The intent-to-treat ANOVA had a significant group effect (p<.02) with CBT being more effective than IH (p<.02), SH (p<.01) and GA (p<.005).

For the treatment efficacy rating CBT showed a significant advantage over GA (p<.002) whilst for treatment dependence, the GA group showed the greatest distress if the treatment was not available (p<.03).

Drop-out rates varied between groups, SH had more than CBT (p<.007) and GA (p<.0001). IH had more than GA (p<.05).

#### Main conclusions of the study authors

A CD with standardised hypnotic suggestions does not show any benefit in the treatment of dental phobia.

Hypnotic suggestion of personalised pleasant imagery was similarly successful and enduring as CBT, however, individualised hypnotic suggestions were characterised by low acceptance.

Limitations of the study are considered to by the lack of true randomisation and that there was a cost to the standardised hypnosis treatment which may have contributed to the fact that there was an immediate 50% drop-out from this group.

### Discussion

#### **Summary of main results**

Trials in this study can be grouped according to the types of participants and types of treatment required:

Trials involving patients with a normal range of anxiety towards dentistry who are undergoing unpleasant or potentially unpleasant surgical dental treatment versus those involving patients assessed as highly anxious or phobic towards dental treatment.

# Summary of results of studies involving patients with a normal range of anxiety levels

These studies included two studies by the same authors which involved patients undergoing implant placement under LA (Eitner et al., 2011, Eitner et al., 2006b). Both report a significant advantage for hypnosis over no hypnosis. Two studies involved patients who received hypnosis in conjunction with IV sedation (Ghoneim et al., 2000, Mackey, 2010) one of which provided a hypnosis tape used for one week before the surgery (Ghoneim et al., 2000) and the other (Mackey, 2010) also used pre-recorded hypnosis but provided it during the surgery. Both report a significant advantage for hypnosis over no hypnosis. Only one of these assessed anxiety as defined in the protocol as a primary outcome (using STAIs) (Ghoneim et al., 2000), whilst Mackey (Mackey, 2010) indirectly assessed anxiety by the measurement of the amount of sedative drug used.

One study (Katcher et al., 1984) compared hypnosis in combination with contemplation in patients undergoing extraction of teeth under LA. This study showed an advantage for hypnosis over no hypnosis, but only when patients were not contemplating an aquarium. Where patients had aquarium contemplation, there was no difference with or without hypnosis. Three studies with the same main author (Enqvist and Fischer, 1997, Enqvist et al., 1995a, Enqvist et al., 1995b) involved patients having surgical treatment under GA only one of which assessed anxiety as a primary outcome measure (Enqvist and Fischer, 1997). These studies showed hypnosis to be effective in one study (Enqvist and Fischer, 1997), whilst the other two gave unclear results.

Due to the heterogeneity of the studies, it is not possible to carry out metaanalysis of the results, but overall it could be concluded that there is weak evidence for the effectiveness of hypnosis in alleviating anxiety for patients undergoing surgical procedures when compared to an untreated control group. However, as the quality of the studies was generally low (see later under quality of evidence), any conclusions must be treated with extreme caution.

#### Studies involving patients with high or phobic levels of dental anxiety

The main characteristics of studies involving such patients are high levels of drop-out behaviour combined with small study groups. All the studies compared hypnosis as a therapeutic intervention before dental treatment with other psychological or behavioural interventions. In these studies, whilst hypnosis was successful in anxiety reduction, it was not significantly better than the range of other methods it was compared to.

All of the studies had significant risks of bias, in particular two studies patients were not adequately randomised (Moore et al., 1996, Moore et al., 2002, Wannemueller et al., 2011). The latter of these studies also had large amounts of missing data.

It must therefore be concluded that there is not enough evidence to suggest that hypnosis is superior to any other method of reducing anxiety towards dental treatment in highly anxious or phobic dental patients. Only one study reported an adverse effect – an increase in the incidence of vomiting in the hypnosis group. The authors give no explanation for this and it seems to be an isolated incidence.

#### **Overall completeness and applicability of evidence**

It is clear from this review that there are significant problems in interpreting the evidence for the effectiveness of hypnosis in anxiety reduction. Many different outcome measures are reported with little cross-over between studies except in physiological measures such as HR and BP, but not all studies report these.

The populations from which participants are drawn are usually from specialised treatment centres such as phobia clinics or oral surgery departments and the patients therefore probably do not reflect the population as a whole. Some studies include patients who suffer from additional psychological and psychiatric disorders and some exclude these, which may be a confounding factor in the results.

#### **Quality of the evidence**

Included studies in this review are mostly at high or unclear risk of bias. No studies reported a sample size calculation and many of the sample sizes were small.

Random sequence generation and allocation concealment are inadequately described in most papers, with only one paper reporting an adequate method of

randomisation. Some studies only randomised some of the participants whilst others used inadequate methods.

Blinding of patients and personnel is difficult in studies involving hypnosis. It is not possible to blind patients because hypnosis is not possible without the patient's knowledge. In addition, if the hypnosis is given at the time of the dental treatment, the presence of the hypnotist will alert all treating personnel to the fact that it has been used. In some studies the hypnotist is also the dentist providing the dental treatment so again, blinding is not possible. The use of tape recorded hypnosis could minimise this potential bias, but sometimes hypnosis participants wore headphones whilst control group patients did not. In the majority of studies it was unclear whether there was blinding of outcome assessors. In most reports this was not acknowledged as a potential or actual issue.

Incomplete outcome data was also prevalent in these studies, although some studies included the number of drop-outs as part of the outcomes of the trial. In addition, selective reporting of data was also identifiable from some of the papers.

There were a large variety of other sources of bias present in the majority of the studies.

#### Agreements and disagreements with other studies or reviews

The findings of this review are similar to a previous review of the use of hypnosis in dentistry for children (Al-Harasi et al., 2010), whereas hypnosis for needle related interventions is concluded to be effective for pain, self-reported

distress and behavioural measures of distress in children (Uman et al., 2006). The review conclusions are also similar to a recently published systematic review which included some but not all of the papers reported here (Jugé and Tubert-Jeannin, 2013).

#### **Authors' conclusions**

#### Implications for practice

On the basis of this review, there is very weak evidence that hypnosis is effective in reducing anxiety towards oral surgery interventions, mainly by the use of hypnosis provided on tape recordings. One study compared standardised tape recorded hypnosis to live individualised hypnosis, but risks of bias within this study make it impossible to draw conclusions on the relative effectiveness of these techniques. The evidence for the effectiveness of hypnosis in reducing the anxiety of highly anxious or phobic dental patients is inconclusive at present, but it may be effective in certain patients.

#### Implications for research

Well designed, properly randomised controlled trials of hypnosis for the alleviation of dental anxiety are lacking. Large scale multi-centre trials including a range of patients would be advantageous.

The selection of measures of baseline anxiety and outcome measures requires attention as it seems that there is no consensus in studies to date about the best measures to use. Although it is recognised that the blinding of patients and personnel is problematic, and may not be possible in these types of trials, at least outcome assessment should be blind. This should be possible in a well-designed study. It would be desirable to have separate studies using different types of hypnotic interventions (e.g. individualised and personalised or standardised and scripted) and methods of delivery (e.g. tape recorded or live).

No treatment control trials would be needed in the first instance followed by comparisons with other non-pharmacological and pharmacological treatment if warranted.

#### **Reflections on the process of the review**

The protocol for this review stated that all RCTs would be included regardless of quality. However, in this chapter some studies have been included which do not qualify as RCTs. This was done for inclusion in this thesis for the sake of completeness. However, for publication of a Cochrane Review, it will be necessary to exclude such trials.

The review process itself aimed to be as comprehensive as possible and was challenging to complete. The results are disappointing for those who use or wish to use hypnosis in their clinical practice and, in particular, there are no trials which investigate hypnosis and inhalation sedation which is the topic of investigation in this thesis.

# **CHAPTER 3**

# **Production of Experimental**

# **Anxiety in the Dental Setting**

# Rationale

The previous chapters have revealed that the evidence for the combination of Inhalation Sedation (IHS) with hypnosis for the reduction of anxiety towards dentistry is lacking. Even though 'expert opinion' suggests that the two techniques may be usefully combined (Coulthard and Craig, 1997, Roberts, 1990), only case studies (Thompson, 1994) and case study series (Shaw and Welbury, 1996) have been published attesting to this. Because of this, the first steps in investigating the relationship must be well controlled and scientifically rigorous. Studies of treatment methods for dental anxiety are difficult in patient populations due to the nature of dental anxiety and phobia, as patients often fail to attend or drop out during clinical trials. In addition, the level of evidence is so low as to raise questions about the ethics and feasibility of proceeding to clinical trials with anxious patients without initial proof-of-concept work. Given that this is the case, the first step is to test these ideas in a non-clinical sample.

If volunteers and non-clinical populations are used, the study will suffer loss of ecological validity which may make the findings difficult to generalise to other populations and to more 'real world' situations, but this is balanced by the ability to more strictly control the experimental conditions. It must be recognised, however, that these drawbacks exist in this type of research in order that unwarranted conclusions are not made in advance of the evidence.

## Production of Temporary Experimental Anxiety

If a non-patient sample is to be used, the first step is to develop a method of reliably producing some temporary dental anxiety in people not attending for dental treatment and to evaluate the method carefully to determine whether it is robust enough to be used in future studies. In normal populations, individuals show a small but significant increase in anxiety levels in dental settings (Dworkin and Chen, 1982), but this would probably not be sufficient on its own. Therefore other ways of producing such temporary anxiety need to be used.

Research into methods of eliciting moods or discrete emotions is widespread (Gerrards-Hesse et al., 1994). One meta-analysis of mood induction procedures (MIPs) aimed to investigate different MIPs on positive and negative mood states and to see whether other issues might influence the outcomes of such studies (Westermann et al., 1996). These authors concluded that MIPs were vulnerable to demand effects, particularly if participants were instructed to try to enter the specified mood. Nevertheless, Film/Story MIPs had high effect sizes even without specific instruction. A more recent meta-analysis (Lench et al., 2011) showed a similar large effect size for film, but this produced only a medium effect size for the emotion of anxiety compared to a neutral state. Feature films have been used and may be effective in producing a variety of different emotions including anxiety (Gross and Levenson, 1995, Hewig et al., 2005, Santagostino et al., 1996). Gross and Levenson (1995) aimed to put together a set of films that could reliably elicit discrete emotions. The clips varied in length from almost 20 minutes to 8 seconds (mean 151 seconds). They used self-report inventories to measure how much of the emotions tested for (amusement, anger, arousal, confusion, contempt, contentment, disgust, embarrassment, fear, happiness, interest, pain, relief, sadness, surprise and tension). The clips used to provoke fear were from the films: The Shining (1minute 22seconds) and Silence of the Lambs (3minutes 29 seconds). They concluded that fear was actually difficult to produce in their experiment as fear was combined with increase in tension and interest.

Several studies involving self-referred anxious and phobic dental patients used video presentations of dental procedures to produce anxiety, enabling the investigation of psychological and physiological reactions of these patients and the outcome of two different treatments for their anxiety (Lundgren et al., 2006, Lundgren et al., 2004, Johnsen et al., 2003).

The film Marathon Man (1976) depicts torture by probing then drilling teeth without anaesthesia. Hewig et al used a short excerpt (2mins 41s) from this as a mood induction in one study (Hewig et al., 2005) and it was found to induce fear and disgust equally in most participants. It may not be possible to separate out the production of anxiety and disgust towards scenes of dental treatment (this effect seems to be more pronounced in women) (Leutgeb et al., 2013), so despite the production of two emotional states, Marathon man, with its concentration on dentistry would seem to be suitable as the MIP stimulus for this study.

#### Measuring dental anxiety

Many self-report scales have been developed to measure the construct of dental anxiety (Newton and Buck, 2000) Also see chapter 2. Unfortunately the agreement between scales is often limited (Locker et al., 1996), raising the question of whether they are measuring the same constructs. Studies using questionnaires based on the DSM-IV definition of specific phobia (Fredrikson et al., 1996, Ragnarsson et al., 2003) seem to detect lower percentages of dental phobia in samples than those based on the available dental anxiety scales. One of the oldest, but probably still the most commonly used in research (Newton and Buck, 2000) is Corah's Dental Anxiety Scale (DAS) (Corah, 1969, Corah et al., 1978b). This simple four item scale gives scores from 4 to 20. Normative data are available for some populations (Neverlien, 1990b) and suggest that a score of 15 is indicative of dental phobia. (Details of this scale are given in chapters 1&2). The Modified Dental Anxiety Scale (MDAS) (Humphris et al., 2000, Humphris et al., 1995) was developed to improve on the DAS by adding an item on local anaesthesia. Possible scores range from 5 to 25 with 19 or over probably indicating dental phobia. Both these scales have good reliability and validity and norms and cut-off points are available for many population groups (Schuurs and Hoogstraten, 1993). High levels of internal consistency (Cronbach's alpha levels all above 0.7) and stability over time (intra-class correlation coefficient of 0.8) are given for the MDAS (Humphris et al., 1995). The sensitivity and specificity of adopting a cut-off of 19 or over are

reported as 0.85 and 0.91. There was a high correlation between the MDAS and the DAS (0.85 p<.001) (Humphris et al., 1995)

A more complex scale is the Dental Fear Survey (Kleinknecht et al., 1973, Kleinknecht et al., 1984) which asks people to rate anxiety towards twenty seven dental situations on a 5 point Likert scale from "none" to "great". The Dental Anxiety Inventory is a 36 item questionnaire (Stouthard et al., 1995), although a short form has also been developed (Aartman, 1998). A single-item measure of dental anxiety - The Dental Anxiety Question (DAQ; 'Are you afraid of going to the dentist?') has been tested and correlates highly with the DAS (Neverlien, 1990a). In one study, participants were simply asked to 'Rate your dental fear on a scale of 1-10' (Gatchel, 1989). All of these scales have been used in research and have been considered to be useful measures, although single item measures have been said to overestimate prevalence of severe dental anxiety (Newton and Buck, 2000).

In some studies, general anxiety scales (e.g. State-Trait Anxiety Inventory; STAI (Spielberger, 1983) have been used in the dental situation rather than dentistry specific measures. The STAI has two parts: the state scale aims to measure anxiety in the present moment and the trait scale aims to measure how often anxiety is felt more generally (i.e., anxiety as an aspect of personality). Each scale has 20 questions with four possible responses. The scale has good reliability and validity, although stability measured by test-retest coefficients is reported as relatively high for the trait scale and low for the state scale (Spielberger, 1983), this should be expected as the state scale should reflect

specific variations over time. Norms are available for many population groups and differences between groups (e.g. clinical groups) are proposed to represent evidence for the validity of the scales (Spielberger, 1983). Mean scores for normal adults aged 19-39 are 35.55 (SD10.22) for males and 36.15 (SD 9.53) for females (Spielberger, 1983)

An early study looked at the relationship between the STAI and the original DAS and found a moderate correlation ( $r_{(63)}$ = 0.48, p<0.001,) between the DAS and the state anxiety scale, but not with the trait scale. The authors suggest that this indicates that the DAS is measuring dental anxiety as an aspect of the individual's current state but that this is a separate construct to their general tendency to experience anxiety (Weisenberg et al., 1974). In contrast, Corah (1986) p.48 argues that the DAS measures "tendencies to appraise dental treatment situations as dangerous and threatening", in other words as a sort of trait dental anxiety distinct from the state anxiety that is experienced by an individual whilst they are in the dental situation.

Other self-report measures of emotional states are visual analogue scales (VAS) and subjective units of distress SUDs scales. VAS scales are normally pencil and paper measures where participants are asked to mark on a line (typically 100mm in length) with labelled anchors at either end (e.g. "no anxiety" at one end and "as anxious as you could ever be" at the other; (Wewers and Lowe, 1990). Further information on the use of such scales is given in chapter 2. SUDs scales are a simple self-report measure of distress experienced during an event or whilst thinking about an event (Wolpe, 1990). They are numerical

scales from 0-10 or 0-100 which ask people to decide how anxious they are at a given point, where 0 is completely non-anxious and 100 is as anxious as they can imagine being. Similar scales have been termed 'verbal rating scales' and are useful when it would be difficult for participants to use a pencil and paper measure like a standard scale or a VAS (Lang et al., 2000).

#### Physiological Correlates of Anxiety

Physiological measurements have been suggested to be more objective than self-report measures, but difficulties have been encountered when these are measured during stressful or anxiety producing situations, particularly when the correlation between physiological and self-report measures have been assessed (Harrison et al., 1985, Morrow and Labrum, 1978). Heart rate has been shown to increase in anxiety producing situations, social anxiety and fear of animals or insects (Kantor et al., 2001, Sartory et al., 1977), but other studies have found more complex relationships in dental anxiety (Harrison et al., 1985, Lundgren et al., 2004). Some studies have suggested that a high level of arousal is necessary before physiological changes become relevant (Lundgren et al., 2006, Sartory et al., 1977). Heart rate changes have also been related to other task situations which demand attention, such as a Stroop Test which produced similar increase in heart rate as viewing dental scenes on video in dental phobics (Johnsen et al., 2003).

An additional variable has been investigated, that of anticipatory anxiety and physiological arousal. This study concluded that baseline measures taken after

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informed consent involving unpleasant experimental procedures may be meaningless (Farha and Sher, 1989).

Despite these limitations, it is useful to have at least one physiological measure of anxiety alongside self-reports.

# **Experiment 1**

#### Aims of experiment

The aim of this experiment was to evaluate whether it is possible to induce temporary experimental anxiety in a dental setting using excerpts from a feature film (Marathon Man,1976), in order that this method can be used in future research into methods of reducing anxiety in non-clinical participants and situations.

Ethical approval for this project was obtained as part of approval for the larger project reported later in this thesis. Approval was from the North Manchester NHS research ethics committee (COREC reference: 06/Q1406/79), confirmed by the University Ethics committee and registered by the Pan Manchester R&D notification form.

The overall aim of the larger project is to compare two ways of reducing anxiety in a dental setting – Inhalation Sedation with Nitrous Oxide/Oxygen mixtures (IHS) with added hypnotic suggestion vs. with neutral verbalisations. As previously explained, healthy (non-anxious) volunteers were to be recruited, so a means of producing sufficient anxiety would be needed to test for any differences between the two methods of anxiety reduction. The film would need to produce reasonably high levels of temporary, experimentally induced anxiety, i.e. have a large effect size, as both methods proposed to be tested could reasonably be expected to reduce anxiety (see chapter 4).

#### Method

#### Design

The experiment used a within subjects, repeated measures design with measurement of anxiety levels and heart rates at baseline in the waiting room, sitting in the dental surgery and whilst watching the film.

#### **Participants**

Volunteers not considering themselves to be dentally phobic were recruited by advertising via student email systems and websites at the University of Manchester. They were reimbursed £5 for their inconvenience and travel. Volunteers were excluded if they self-identified as having a pre-existing psychological condition and if they scored above 19 on the MDAS (potentially indicating dental phobia (Humphris et al., 1995)). In addition, volunteers were medically fit and well (ASA I or II (Malamed, 1995)

#### Materials

#### Questionnaires

• The trait scale of the STAI (Spielberger, 1983) to give a measure of the participant's general levels of anxiety

- The Modified Dental Anxiety Scale (Humphris et al., 2000; Humphris et al., 1995) to measure 'trait dental anxiety' as this is easy and quick to fill in and gives a reliable indication of the anxiety status of participants and a way of identifying those who may be dentally phobic. Volunteers scoring 20 or above were excluded from the study as a safety measure to prevent exacerbation of their dental anxiety
- SUDs 0-100 scale where 0 represents relaxed and calm and 100 represents as anxious as they could imagine ever being. A SUDs scale was chosen as it makes it easy to identify rapid changes in anxiety and does not interfere with watching the film or looking around the experimental setting. A visual analogue scale (VAS) scale would demand that the participant concentrate and use pen and paper to record their anxiety whereas a SUDs scale can be reported verbally. This study used a 1 to 100 SUDs scale to allow participants a greater range of responses than 0-10
- All of the above scales measure some aspect of the situation or the characteristics of the person that may contribute to anxiety experienced by our participants and relationships or correlations between them will be analysed
- A Manchester Dental Hospital standard medical history form for the exclusion of participants who are not fit and well.

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#### Equipment

Pulse oximeter to measure heart rate every 30 seconds (timed with a stopwatch). The pulse oximeter is a device which measures the oxygen saturation of the blood by means of a sensor placed on a finger. It also gives readings of the heart rate at the same time. The measures of heart rate were divided into time periods related to the phases of the experiment and mean heart rates calculated for each stage.

DVD player to show two selected, non-consecutive excerpts from Marathon Man

Various dental instruments including needle and syringe, endodontic kit and forceps which was set out in the surgery as if it was to be used. This was to make the dental surgery set up more realistic (i.e., as if treatment was to be carried out) in order to maximise the anxiety provoked by the situation. The two excerpts from the film were chosen because of their content. These sections of the film involve the use of dentistry as a form of torture to attempt to obtain information from the hero of the film. The first section shows him tied to a chair whilst another person asks a question (is it safe?) to which he does not know the answer. There is a build-up of tension as dental instruments are laid out and the questioner washes his hands in preparation for using the instruments.

He then looks inside the mouth of the prisoner and probes his teeth commenting on finding a cavity which he probes deliberately, producing severe pain. The segment concludes with the application of oil of cloves to the tooth (thus relieving the pain) and the threat of future pain if he does not cooperate. The second excerpt continues the theme, but instead of a probe the torturer sets up a drill and drills into a healthy tooth. The actual dental 'treatment' is not shown. Instead, the viewer hears the sound of the drill and the scream of pain. However; the power of the clips lies in the building anticipation of the pain production rather than 'gore' per se.

#### Setting

The STAI-trait and the MDAS together with a standard hospital medical history form were administered online (i.e. not in a dental environment). The test setting was a dental surgery equipped for provision of inhalation sedation within the children's department of the Manchester Dental Hospital.

#### **Outcome Measures**

The outcome measures were recordings on the 0-100 SUDs scale for measuring changes in anxiety during the procedure (measured after sitting in the waiting room for 2½ minutes, after sitting in the dental chair for 2½ minutes and after watching the film) and the pulse rate measured at 30second intervals for 5 minutes in the waiting room, 5 minutes in the dental surgery and for the duration of the film clips from a standard pulse oximeter by a research assistant using a stopwatch to time the readings. The choice of physiological measure was made on a pragmatic basis. Pulse rate was the most convenient measure, as

simple equipment was readily available to measure this. The SUDs scale was administered and recorded by the experimenter.

#### **Procedure**

Participants volunteered and filled in the consent form, medical history form, STAI(T) and MDAS online and were then invited to attend for the experiment providing they fitted the criteria. When they attended they signed the consent form in the presence of the experimenter. Their pulse rate was measured for 5 minutes in the waiting room and the rate was recorded every 30 seconds. Half way through the 5 minute period they were asked to rate their anxiety on a scale of 1 to 100, where 1 represented no anxiety and 100 as anxious as they could imagine ever being. They were then invited into the dental surgery setting and seated in the dental chair; their heart rate was monitored as before and their anxiety again assessed after  $2\frac{1}{2}$  minutes. They then watched the excerpts from the film, which lasted approximately 7 <sup>1</sup>/<sub>2</sub> minutes. Their heart rate was monitored throughout this. Anxiety was assessed at the end of the film, asking them to rate the most anxious they had felt whilst watching the film. The participants were then debriefed, given the opportunity to ask any questions about the study and assured that they would be able to contact the experimenters if they wanted or needed to following the experiment.

#### Statistical Analysis

Results were analysed using the statistical package SPSS for windows v.13.

# **Hypotheses**

- That there will be significant changes in anxiety as measured by a 1-100 SUDs scale between the waiting room and sitting in the dental surgery.
- 2. That there will be significant changes in anxiety as measured by a 1-100 SUDs scale between time 1(sitting in the waiting room) and time 3 (immediately after watching the film) and between time 2 (sitting in the dental surgery) and time 3 (immediately after watching the film).
- 3. There will be related increases in mean heart rate at the same three periods.
- The changes in anxiety levels will be correlated with scores on the MDAS and the trait anxiety measured by STAI(T).

#### Results

#### **Participants**

Volunteers were recruited between 15<sup>th</sup> January and 7<sup>th</sup> February 2007, resulting in 151 online forms being returned. The first 68 volunteers were checked for inclusion in the study. Of these 12 were excluded due to missing data and 7 were excluded as their MDAS scores reflected possible dental phobia. Of the remainder, 49 were invited to attend and 29 actually attended. The participants who were not invited were invited to attend for a later experiment. The only difference between those who attended and the remainder of the volunteers (group 2 – invited but did not attend, group 3 - excluded dental phobia, group 4 – excluded incomplete data and group 5 – not invited) was that attendees had a higher mean age than the sample as a whole (24.69 years and 22.16 years respectively). This was statistically significant (one-way ANOVA post-hoc Bonferroni test 95% CI .51-6.78 p = .011).

Figure 1 Flow chart of phases of experiment 1

<b>Recruited</b> online	n=151					
Checked for inclusion	n=68					
Excluded						
Missing data	n=12					
Dental phobia	n=7					
Invited to attend	n=49					
DNA	n=20					
Attended	n=29					
Included in analysis	n=29					

Remaining analysis will be confined to those who attended. Twenty were female (69%) and nine (31%) male. Their ages ranged from 18 to 54 (mean 24.69 SD 8.544). Their scores on the modified Dental Anxiety Scale (MDAS) ranged from 6 to 18 (mean 12 SD 3.207). Their scores on the State – Trait Anxiety Inventory (Y2, trait scale) ranged from 22 to 61 (mean 39.90 SD 8.88). (Table 36) Tests of normality confirmed that the data were not normally distributed and transformations of the data were not successful in producing normal distributions; analyses were therefore carried out using non-parametric methods.

Table 36 Age, MDAS scores and STAI(T) scores of participants

	95% Confidence Interval for Mean						
	N	Mean	SD	Lower bound	Upper bound	Min	Max
Age in years	29	24.69	8.54	21.44	27.94	18	54
MDAS score	29	12	3.2	10.78	13.22	6	18
STAI(T) score	29	39.9	8.88	36.52	43.27	22	61

# **Self-Reported Anxiety Levels**

The descriptive statistics for the scores on the SUDs scales at time point 1 in the waiting room, time point 2 in the surgery and time point 3 after the film are given in table 37. They are not normally distributed.

Table 37 self-reported	anxiety levels at	t three time points
------------------------	-------------------	---------------------

SUDs scores					
Anxiety Scores	Median	Interquartile Range	Min	Max	Range
Time point 1 Waiting Room	25	35	2	65	63
Time point 2 Surgery Time point 3 Film	25 40	44 41	5 5	75 85	70 80

A Freidman's ANOVA revealed a highly significant change in reported anxiety

levels between the waiting room, dental surgery and after the film

(χ2(2)=28.784 p<.001).

Post-hoc Wilcoxon signed ranks tests revealed that the difference in anxiety levels between the waiting room and surgery were non-significant, but both the difference between the waiting room and after the film and between the surgery and after the film were significant (anxiety film-anxiety waiting room z = .-4.072 p<.0001; anxiety film-anxiety surgery z = -3.717 p<.0001). At a critical significance of 0.0167 rather than 0.05 (using the Bonferroni correction for 3 comparisons) these results are still highly significant. Figure 1 shows the changes in median self-reported anxiety levels (SUDs scores) over the course of the experiment.

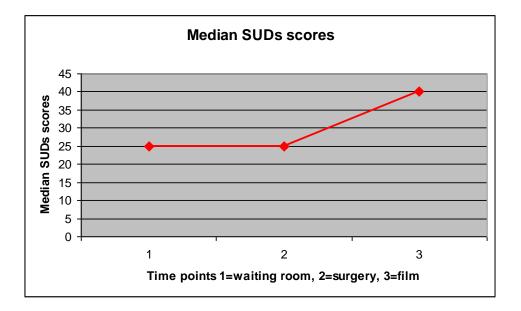


Figure 2 Graph of changes in median self-reported anxiety levels

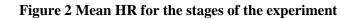
An effect size for the anxiety produced by the film is needed in order to compare the effect of this film to other studies. Since the change in anxiety from the waiting room to the surgery was not significant, an effect size for the film was calculated using the Wilcoxon test of the difference from the surgery to after the film using the method recommended by Field (2005). This revealed a medium effect size of r = 0.49 (accounting for at least 9% of the variance) for the film.

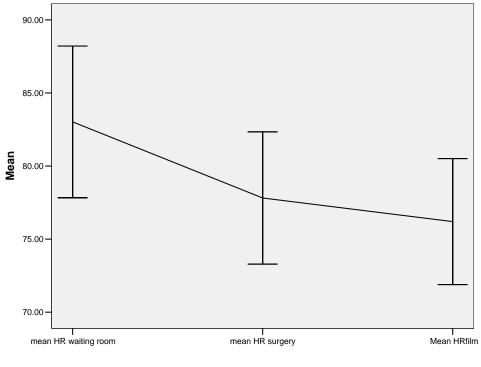
# **Heart Rate**

Mean heart rates were calculated for the time periods in the waiting room, in the surgery and during the film and are shown in table 38 and in figure 2.

Table 38 descriptive statistics of the mean heart rates during the experiment N=29

	N	Range	Minimum	Maximum	Mean	Std Deviation
Mean heart rate in waiting room	29	54.3	57.3	111.6	83.02	13.65
Mean heart rate in surgery	29	43.3	55.9	99.2	77.81	11.89
Mean heart rate watching the film	29	39.04	54.46	93.5	76.2	11.33





Error bars: 95.00% CI

A repeated measures ANOVA was carried out to determine whether these changes were significant. Mauchly's test indicated that the assumption of sphericity had been violated ( $\chi 2$  (2) 18.206, p<.001) so degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity. This showed that there was a significant change in mean heart rate across the three phases of the experiment. The decrease in heart rate is significant between the waiting room and surgery (p<.001 and between the waiting room and the film (p<.001) but not between the surgery and the film.

#### Correlations

Correlations were explored between MDAS and STAIT scores, MDAS scores and anxiety scores at all three times and STAIT scores and anxiety scores. The only significant correlation was between STAIT score and the anxiety score after watching the film. This is a moderate effect with a Spearman rank-order correlation coefficient of .463.

 Table 39 Correlation between STAI (trait) score and anxiety level after watching

 the film

			STAIT	Anxiety score film
Spearmans's	STAIT	Correlation	1.000	.463*
rho		Coefficient		
		Sig. (2-tailed)		.011
	Anxiety score	Correlation	.463*	1.000
	film	Coefficient		
		Sig. (2-tailed)	.011	

\*correlation is significant at the 0.05 level (2-tailed)

There were no significant correlations between heart rate and anxiety levels at any time period, nor heart rate and MDAS or STAIT scores

#### Discussion

#### Sample demographics

The age of the participants who attended was significantly older than the volunteers as a whole. As the older volunteers were staff members and postgraduate students, this may reflect that if they volunteer, they decide to do so earlier and are more likely to attend when invited than younger, mainly undergraduate students.

Dental anxiety as measured by the MDAS is reasonably stable in these age groups and only declines after age 60 (Humphris et al., 1995). The mean MDAS score of the participants in the present study was 12 which is very similar to the mean score of 11.73 obtained from first year psychology students and for adult female general practice attenders (12.87) in a study to establish UK norms (Humphris et al., 1995). This is despite the fact that seven volunteers were excluded due to high scores (20 or above) on the MDAS which might indicate extreme or phobic levels of dental anxiety. The mean MDAS score of the whole sample of volunteers was somewhat higher at 13.5, although the difference between the volunteers as a whole and the participants who attended was not statistically significant. The trait anxiety scores for all the volunteers measured by the STAIT (42) were a little higher than the normative data reported for college students (38.3 for males, 40.4 for females) and working adults: (34.89 for males and 34.79 for females) (Spielberger, 1983), except in the group that attended (mean 39.90). The majority of the volunteers were women, which may affect the mean scores on the MDAS and STAIT, as the

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population norms for these scales suggest that, women consistently report being more anxious than men on the MDAS measure (Humphris et al., 1995) and the STAIT scale (Spielberger, 1983).

In the group of participants who attended, there was no significant correlation between the scores on the MDAS and the STAIT. This is in line with previous findings for dental anxiety scales (Weisenberg et al., 1974). Trait anxiety was significantly correlated with anxiety levels after the film, but not with the changes in anxiety from waiting room to after the film or from surgery to after the film. Dental anxiety (MDAS scores) levels also did not correlate with anxiety levels or changes.

The correlation between the anxiety levels after the film and trait anxiety is in line with what would be expected, although it might have been expected that there would also have been a relationship between changes in anxiety and both trait and dental anxiety, so hypothesis 4 is only partially supported.

#### **Self-Reported Anxiety Levels**

The film produced a highly significant increase in self-reported anxiety levels but simply being in the dental surgery did not. This is surprising, as other studies have suggested that, even in non-dentally anxious individuals the dental environment is associated with anxiety even when dental treatment is not planned (Dworkin and Chen, 1982). Hypothesis 1 is therefore not supported, but hypothesis 2 is supported. This may, in part, be due to the setting used for the experiment which was the children's department where surgeries are painted and decorated in ways designed to look non-threatening. In fact, several participants commented on the pleasant surroundings and said that it was impossible to feel anxious despite the display of instruments and the dental environment.

The increase in anxiety produced by the film compared to the anxiety in the dental surgery was highly statistically significant, and although the effect size was moderate to high the variability was also high. The minimum anxiety level reported for during the film was 5 and the maximum 85 median 40 and interquartile range 41. Although this would show a difference between a treated group and a control with approximately 85 participants (Field, 2005), the anxiety levels produced may not be sufficient to show a difference between two groups who have both had an anti-anxiety intervention. That is, in later stages of the project as planned (see later), the effect of the nitrous oxide alone may remove the experimental anxiety and leave no room to show any extra effects of hypnosis.

#### **Heart Rate**

Hypothesis 3 was not supported as for all subjects the heart rate reduced over the time of the whole experiment. The initial high measurements could simply be due to the fact that the experiment took place on the second floor of the building so heart rates reduced as people were sitting down and resting. The fact that the heart rates measured in the surgery were initially high and reduced over time suggests that there is an exercise effect.

Another possibility is that the high initial heart rates represent anticipatory anxiety about the possible effects of the experiment. This has been

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shown to be a powerful effect (Farha and Sher, 1989) and these experimenters suggest that baseline measures are meaningless if taken following informed consent procedures.

The significant reduction in heart rate whilst watching the film is unexpected as anxiety levels were reported to be higher, so some correlation may have been anticipated. However, in other studies it has been difficult to show correlations between heart rate and reported anxiety levels (Harrison et al., 1985, Moon and Cho, 2001, Morrow and Labrum, 1978). In addition the film clip used is approximately 7 minutes long, but the clip contains only two incidents that show extreme actions (probing the painful tooth and drilling the healthy tooth) expected to arouse acute anxiety, each lasting about 1 or 2 minutes. Because of the difficulty in setting a DVD to start and finish at exact times, it is not possible to match the heart rates for each individual subject exactly to those parts of the film; therefore it is possible that the apparent randomness of the heart rate changes during the film may be caused by measurement variations.

An alternative explanation is supported by one study which has shown that watching a virtual reality video in the dental setting during treatment failed to reduce anxiety levels but significantly reduced the heart rate of participants (Sullivan et al., 2000). This may indicate that the heart rate lowering is related to absorption in the film and not related to the emotions produced either by the film or by the dental setting.

In other studies using heart rate as an outcome variable, much more sophisticated equipment has been used than the simple manual recording every

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30 seconds used in this study. It is therefore possible that this method is not sensitive enough to pick up significant changes.

#### **Conclusions**

This study has been very useful in identifying problems that may have prevented the main study from identifying any significant results regardless of the number of participants recruited to take part. The major problem is that the film did not reliably produce sufficient anxiety to be able to allow comparison of two methods of reducing dental anxiety. One possibility is that a shorter film with more concentrated upsetting scenes would produce more robust increases in anxiety. Since the dental setting provoked compliments from participants on how pleasant it was, it would seem advisable to move the experiment into a more traditional dental hospital setting on the ground floor (to avoid exercise effects on pulse rate) such as the oral surgery department. Finally, the baseline measures should be taken at the end of the experiment rather than the beginning as recommended by Farha and Sher (1989).

For all these reasons, a second experiment addressing these issues was planned.

# **Experiment 2**

#### Introduction

This experiment was designed to overcome the shortcomings of experiment 1. Firstly, a new anxiety stimulus was constructed consisting of a shorter sequence with much more concentrated unpleasant scenes taken from Marathon Man and two other relevant films with short scenes from two films from the horror genre, The Dentist and The Dentist 2 (1996, 1998). The films were viewed and suitable scenes identified. The film sequences were edited together using MPEG video wizard DVD (©1998-2008) to produce a single video which lasted for 4 minutes 50 seconds. Secondly, the experiment was relocated to the oral surgery department on the ground floor of the hospital which is not decorated in ways designed to make children feel at ease.

Lastly, baseline pulse rates and anxiety levels were taken when the experiment was over to investigate whether anticipation was affecting the results.

#### **Methods**

#### Design

The experimental design was a within subjects, repeated measures design with measurement of anxiety levels (with a SUDs scale) and heart rates sitting in the dental surgery (time point 2), whilst watching the film (time point 3) and two baseline measures – on arrival before entering the dental surgery (time point 1 and after debriefing (time point 4).

#### Setting

The STAI-trait and the MDAS together with a standard hospital medical history form were administered online (i.e. not in a dental environment). The test setting was a dental surgery equipped for provision of inhalation sedation within the oral surgery department of the Manchester Dental Hospital.

#### **Participants**

The volunteers from the previous study who were not invited at that stage were re-contacted by email and asked if they still wished to participate and the experiment was publicised on the University of Manchester research volunteering website. As before, they were reimbursed £5 as in the previous experiment for their inconvenience and travel. Inclusion and exclusion criteria were identical to experiment 1.

#### Materials

#### Questionnaires and Equipment

The questionnaires and equipment were identical to experiment 1 with the exceptions described below. The film was shown on a laptop computer rather than a television with DVD player as previously. This was necessary because of the format of the film recording. The sound was played through headphones rather than speakers due to the venue being adjacent to a patient treatment area. A new film was constructed composed of several short clips rather than two longer ones. Shorter excerpts from Marathon Man were chosen removing the buildup from the previous scenes. The two horror films were watched and suitable scenes added to the two original scenes. These were much more graphic in nature, including mock intra-oral shots showing drilling, extractions and injections. The total length of the film was 4 minutes 50 seconds.

#### **Outcome Measures**

The outcome measures were recordings on the 1-100 SUDs scale for measuring anxiety levels during the procedure and pulse rate measured at 30second intervals from a standard pulse oximeter by a research assistant using a stopwatch to time the readings. The SUDs scale was administered by the experimenter.

#### Procedure

Participants volunteered and filled in the consent form, Medical history form, STAI (trait) and MDAS online and were then invited to attend for the experiment providing they fitted the criteria. When they attended they signed the consent form in the presence of the experimenter in the waiting room. A baseline anxiety score was taken using the SUDs scale of 1 to 100, where 1 represented no anxiety and 100 as anxious as they could imagine ever being. They then entered the dental surgery where their pulse rate was monitored for 5 minutes and the rate was recorded every 30 seconds. Half way through the 5 minute period they were asked to rate their anxiety on the SUDs scale. They then watched the film for 4 minutes 50 seconds. Their heart rate was monitored throughout this time and recorded at 30 second intervals with an extra recording at the end of the film. Anxiety was assessed at the end of the film, asking them to rate the most anxious they had felt whilst watching the film. The participants were then debriefed, given the opportunity to ask any questions about the study and assured that they would be able to contact the experimenters if they wanted or needed to following the experiment. They then sat quietly in the dental chair

and their heart rate monitored for another 5 minutes with a SUDs scale anxiety measure half way through the period.

# **Hypotheses**

- That there will be a significant increase in anxiety as measured by a 1-100 SUDs scale between time 2 (sitting in the dental surgery) and time 3 (immediately after watching the film).
- There will be a significant decrease in anxiety as measured above between after the film (time 3) and at the end of the experiment (time 4).
- 3. There will be a significant decrease in anxiety between time 1 and time 4 due to decrease in anticipatory anxiety.
- 4. There will be related increases in mean heart rate from the dental surgery to during the film and heart rate will reduce at baseline after the conclusion of the experiment.
- The changes in anxiety levels will be correlated with scores on the MDAS and the trait anxiety measured by STAI (trait).

#### Results

## **Participants**

Twenty eight volunteers returned consent forms and questionnaires and were invited to attend. Only one person who replied was excluded due to possible dental phobia. Twenty two participants attended and six either did not attend or cancelled their appointments. There were no significant differences between the group that attended and those who did not, except that the group who failed to attend or cancelled their appointments had significantly higher scores on the STAIT scale (attendees: mean 39.48 SD 6.99, PCA/DNA: mean 47.4 SD 9.99, t = -2.103 p = 0.046 95% CI for the difference -15.70 to -0.15).

Figure 4 Flow chart of phases of experiment 2

<b>Recruited online</b>	n=29						
Excluded							
Dental phobia	n=1						
Invited to attend	n=28						
DNA	n=6						
Attended	n=22						
Included in analysis	n=22						

Remaining analysis will be confined to those who attended. Sixteen were female and six male. Their ages ranged from 19 to 35 (mean 23.64 SD 3.553). Their scores on the modified Dental Anxiety Scale (MDAS) ranged from 6 to 18 (mean 11.5 SD 2.988). Their scores on the State – Trait Anxiety Inventory (Y2, trait scale) ranged from 26 to 52 (mean 39.467 SD 6.990). Although females had higher STAIT scores and lower MDAS scores, these differences were not significant.

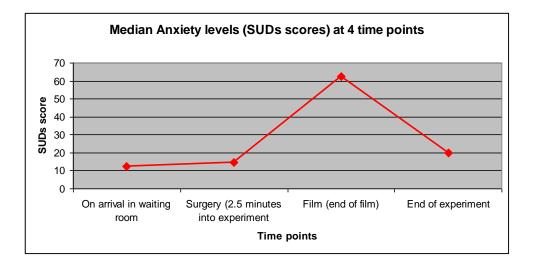
# **Self-Reported Anxiety Levels**

The descriptive statistics for the scores on the SUDs scales in the waiting room, surgery, film and after the film are given in table 40. Except for the anxiety levels during the film they are not normally distributed as shown by significant results of the Kolmogorov-Smirnov test: (waiting room: D(22) = 0.25, p .001, surgery D(22) = 0.28, p .002 and at the end D(22) = 0.28, p .000). Transformations of the data did not correct this. Because of this, non-parametric analyses were conducted.

Anxiety Scores	Median	Interquartile Range	Min	Max	Range
On arrival in waiting room time point 1	12.5	38.5	1	85	84
Surgery (2.5 minutes into experiment) time point 2	14.5	40	2	70	68
Film (end of film) time point 3	62.5	47.25	10	100	90
End of experiment time point 4	20	31	1	75	74

#### **Table 40 Descriptive statistics for SUDs scores**

Figure 5 median Anxiety levels at four time points



The differences between SUD scores at the different times in the experiment were investigated revealing a significant increase in reported anxiety between the scores at the end of the film (time point 3) compared with all other reports. Wilcoxon signed ranks tests gave the following results: anxiety film-anxiety waiting room z = .-3.698 p<.000; anxiety film-anxiety surgery z = -4.019p<.000; anxiety end-anxiety film z = -4.110 p<.000. At a critical significance of 0.0125 rather than 0.05 (using the Bonferroni correction for 4 groups) these results are still highly significant.

The effect size for the film was calculated using the Wilcoxon test of the difference from the surgery to after the film using the method recommended by Field (2005) as in Experiment 1. The effect size was very large r = 0.86 (accounting for at least 25% of the variance).

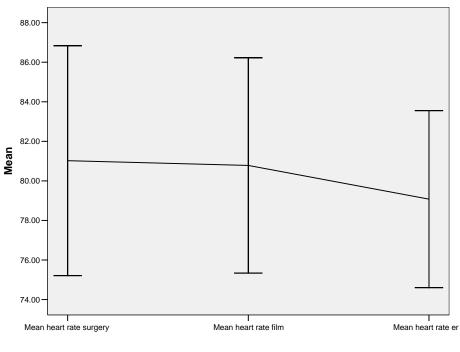
#### **Heart Rate**

Mean heart rates were calculated for the time periods in the surgery (time 1), during the film (time 2) and for 5 minutes at the end of the experiment (time 3) and are shown in table 41 and graphically in figure 4.

Table 41 descriptive statistics of the mean heart rates during the

		Median	Minimum	Maximum	Mean	Std. Deviation
time 1	Mean HR surgery 5 minutes resting in dental chair	82.1	54.2	108.6	81.02	13.11
time 2	Mean HR whilst watching film -	80.65	52.7	106.3	80.78	12.28
time 3	Mean HR 5 minutes resting at end in dental chair	81.6	54.7	99.8	79.08	10.09

#### experiment n=22



Error bars: 95.00% CI

#### Figure 6 Mean heart rates for all participants at each time period

Paired t-tests indicated that there were no significant differences between any of the time points, although the difference between time one and 3 approached significance (time 1 and 2 t=.206 p=.839, time 2 and time 3 t=-1.357 time 1 and time 3 t=.189 p=.055).

#### Correlations

Correlations were explored between MDAS and STAIT scores, MDAS scores and anxiety scores at all three times and STAIT scores and anxiety scores. MDAS scores and STAIT scores were not significantly correlated. MDAS scores were significantly correlated with anxiety scores in the waiting room ( $r_s = .552 p = .008$ ) and in the surgery ( $r_s = .585 p = .004$ ), which were large effects. There was no significant correlation with anxiety during the film or after the experiment. MDAS also revealed no significant correlations with changes in anxiety produced by the film. STAIT scores did not correlate with anxiety levels at any time.

#### Discussion and comparison with experiment 1

#### Heart Rate

The heart rate data again did not show any significant effects. Hypothesis 3 was therefore not supported.

The significant drop in heart rate which was proposed to be an exercise effect in the first experiment was absent in experiment two, supporting the idea that the flights of stairs to the venue were responsible for this. Overall, the heart rate still declined during the course of the experiment, although this was not significant. The modest decreases in heart rate may be due to reduction in anticipatory anxiety (Farha and Sher, 1989) or absorption in the film (Sullivan et al., 2000) as discussed earlier. Alternatively, measurement error, or random variations may have been responsible.

#### **Anxiety levels**

The self-report anxiety data showed that there were no significant differences between anxiety levels before the experiment started, in the dental surgery and at the end of the experiment, although there were small changes (median for the waiting room = 12.5, median for the surgery = 14.5, median at the end 20) the first two being in line with what would be expected: a small amount of anticipatory anxiety rising slightly in the dental surgery environment. However, the highest median level is at the end of the experiment which is unexpected. This could represent some residual anxiety from watching the film.

Hypotheses 1&2: that there will be a significant increase in anxiety as measured by a 1-100 SUDs scale between the dental surgery and watching the film and there will be a significant decrease in anxiety as measured above between after the film and baseline at the end of the experiment were supported.

The increase in anxiety produced by the new film was highly significant with a much larger effect size than the previous version, although the variability was still high.

#### Correlations

Contrary to expectation, there was no correlation between anxiety produced by the film with scores on the MDAS and the trait anxiety measured by STAI(T). The only significant correlation was between MDAS and anxiety scores in the waiting room and in the surgery. This could be related to anticipatory anxiety being higher in those with greater anxiety about dentistry. In addition, the scores on the MDAS and the STAI(T) were not correlated in this sample. It may be that this sample is too small to show the moderate correlations which have been shown between dental and general anxiety in the past.

#### **Measurement issues**

The heart rate measure used was shown not to be useful for the purposes of this experiment. The observed variations appear to be variations between people, unrelated to their reported anxiety levels. The main criticism of the method

used is that it was a crude measure at best, as no automated method of measurement was available and furthermore, heart rate may not be the preferred physiological measure of anxiety levels (Morrow and Labrum, 1978, Moon and Cho, 2001, Harrison et al., 1985).

# **Conclusions**

This experiment has confirmed that a suitable level of temporary experimental anxiety can be produced by watching these selected excerpts from feature films. As the calculated effect size is considered large Field (2005) suggests that 28 subjects would be needed in an experiment to detect this size of effect. A sample size calculation for the experiment in the next stage of the project is given in chapter 4.

This film will be used in the next stage of this project to investigate two methods of using inhalation sedation with nitrous oxide and oxygen (IHS) to reduce anxiety. There will be two conditions, one in which participants have IHS combined with hypnosis and the control condition where IHS is combined with a neutral recording of a story.

# **CHAPTER 4**

# Does the Addition of Hypnosis to Inhalation Sedation with Nitrous Oxide Reduce Experimental Dental Anxiety more than Inhalation Sedation Alone?

# Introduction

Dental anxiety remains a common problem which may prevent people from seeking the dental treatment they need, or lead to them being unable to receive treatment in the dental surgery. A previous Adult Dental Health Survey showed that around a third of those surveyed agreed that they were 'always anxious about going to the dentist', rising to 46% of irregular attenders (Nuttall et al., 2001); the most recent survey showed that 12% of those surveyed reported extreme dental anxiety on the Modified Dental Anxiety Scale (MDAS (Humphris et al., 1995), with a further 36% reporting moderate anxiety. Sadly, younger adults were more likely to be extremely anxious than older adults suggesting that this is a problem which is not reducing over time (NHS, 2010). Furthermore, anxiety was found to be a barrier to receiving regular dental care in the Adult Dental Health survey (Hill et al., 2013).

Sedation and hypnosis are two techniques that have been used to reduce anxiety towards dentistry. Their combination was suggested in the Poswillo report which, as reported in chapter 1, considered the need for the use of general anaesthesia and sedation in dentistry outside hospitals and recommended that, in dental sedation, the drugs should be used "to reinforce hypnotic suggestion and reassurance" (Poswillo, 1990) (p.6).

There is a general acceptance of the fact that suggestion, hypnotic or semi– hypnotic, is important in the success of inhalation sedation techniques using nitrous oxide/oxygen mixtures (Roberts, 1990). However, little systematic investigation of the relationship between hypnosis and Inhalation Sedation (IHS) has been reported in the literature and evidence for the clinical use of their combination is limited to case series and case reports (Shaw and Welbury, 1996, Thompson, 1994).

An early paper investigated the effect of nitrous oxide on the acceptance of hypnotic suggestions in volunteers and concluded that nitrous oxide/ oxygen mixtures increased the likelihood of successful response to suggestions (Barber et al., 1979), but the study was small, and only three suggestions were presented. Whalley and Brookes (2009) investigated the modification of imaginative suggestibility (which is closely related to hypnotic suggestibility) and imaginative ability using 25% nitrous oxide 75% oxygen. They concluded that, in unselected volunteers, the inhalation of the nitrous oxide/oxygen mixture increased imaginative suggestibility and ability and moreover, participants who scored in the mid-range of suggestibility without nitrous oxide exhibit the largest improvements in imaginative suggestibility. This finding could be important as the majority of the population scores in this mid range of suggestibility. However, in this study participants were told that it was not a study of hypnosis which may affect the results, as others have found that the label 'hypnosis' is important in the response to suggestion (Gandhi and Oakley, 2005).

Research has been carried out showing that the effects of nitrous oxide/oxygen mixtures on pain perception can be altered by giving information designed to increase expectations about its effects (Dworkin et al., 1983b, Dworkin et al., 1984). Expectancy of this sort has also been shown to be important in hypnotic

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responding (Wickless and Kirsch, 1989). In addition, pain has been shown to provoke more anxiety in a dental surgery setting and volunteers in the dental setting had lower pain threshold and pain tolerance than those in a laboratory setting (Dworkin and Chen, 1982). See chapter 1 for more details of this work. The GDC no longer give specific guidance on sedation, but previous GDC guidelines stressed that sedation should be used with caution having due regard for other psychological strategies and that the decision to use sedation should be taken after other measures have been attempted:

"In assessing the needs of an individual patient, due regard should be given to all aspects of behavioural management before deciding to refer, to prescribe or to proceed with treatment." (Section 4.9 (2001))

Dentists also need to take steps to minimise the amount of drug used to enable treatment to proceed:

"A dentist ... must ... ensure that the method and nature of the conscious sedation chosen is the most appropriate to enable treatment to be carried out for the patient as an individual, taking into account specific factors such as age, state of health, social circumstances and special needs. The choice of techniques and drugs used should be governed by the principle of minimum intervention and the amount of any drug administered should be the minimum necessary to achieve the desired effect." (Section 4.14 iii (2001)) Studies exploring hypnosis combined with intravenous sedation have shown that less drug is required to produce adequate sedation (Dyas, 2001, Mackey,

2010). However, there have been no studies investigating whether this also

applies to IHS and hypnosis. If hypnotic suggestion enables more patients to benefit from IHS or makes IHS more effective, possibly reducing the amount of drug needed to produce adequate sedation, hypnosis would be an important addition to techniques available to dentists who use sedation.

Anxiety measurement during inhalation sedation has not previously been carried out, so there is no precedent estimate of anxiety reduction due to either sedation or hypnosis during treatment. Most studies have concentrated on changes in dental anxiety measured before and after a behavioural intervention aiming to help the patient to allow treatment and sometimes after dental treatment has been carried out. Some have also taken long term follow up measures to see if patients continue to attend (for reviews see Kvale, Berggren, & Milgrom (2004) and Gordon et al (Gordon et al., 2013).

Due to the lack of studies in this area, it is unknown whether adding hypnosis to IHS actually produces a greater reduction in anxiety in the dental setting than IHS alone. In order to address this, two studies were conducted evaluating the anxiety produced by the film described and evaluated in the previous chapter in participants receiving IHS whilst listening to a story, compared to those who received IHS combined with hypnosis.

# **Experiment 1**

#### Methods

Ethical approval was obtained for the whole of this project from the North Manchester committee: COREC reference: 06/Q1406/79, which was

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subsequently ratified by the University of Manchester Ethics committee and registered using the Pan Manchester R&D notification form.

#### Design

The experiment used a single blind between subjects, repeated measures design. The dependant variable was self-reported anxiety using a SUDs scale. The within subjects factor was time, which had five levels (time 1 [sitting in the dental surgery] vs. time 2 [after a physiologically and psychologically comfortable level of sedation was reached] vs. time 3 [after listening to the story or hypnosis], vs. time 4 [after watching the film] vs. time 5 [at the end of the experiment]). The between subjects independent variable was condition, which had two levels: control [IHS plus a story] versus intervention [IHS plus hypnosis].

#### Setting

The test setting was a dental surgery equipped for provision of inhalation sedation within the oral surgery department of the Manchester Dental Hospital.

#### **Participants**

Volunteers not considering themselves to be dentally phobic were recruited by advertising via student email systems and websites at the University of Manchester. They were reimbursed £10 for their inconvenience and travel. Volunteers were excluded if they had a pre-existing psychological condition as revealed by relevant questions on the medical history form and if they scored above 19 on the MDAS (indicating possible dental phobia). In addition, volunteers had to be medically fit and well (ASA I or II (Malamed, 1995)) as assessed by the medical history form. (ASA I: A patient without systemic disease; a normal healthy patient ASA II: A patient with mild systemic disease which does not affect the patient's lifestyle.)

#### **Materials**

#### Questionnaires and information sheets

The following questionnaires or scales were used:

Modified Dental Anxiety Scale (MDAS) (Humphris et al., 2000, Humphris et al., 1995)

Trait form of the Spielberger State Trait Anxiety Inventory (STAIT) (Spielberger, 1983)

The outcome measure was a SUDs scale of anxiety as described in chapter 3, ranging from one to one hundred, with one representing the "most relaxed and non-anxious as you can imagine ever being" and one hundred representing "as anxious as you can imagine ever being".

The Manchester Dental Hospital standard medical history form

Three separate information sheets were developed. The first outlined the experiment described as "A study to investigate the effect on experimental dental anxiety of sedation with a mixture of nitrous oxide and oxygen combined with listening to tape recordings". See Appendix 3 for full text.

The second and third were specific to each group. One explained the effects of inhalation sedation using nitrous oxide/oxygen mixtures describing it as an

effective method of reducing pain and anxiety in dentistry and as a generally pleasant experience. The wording of this information sheet was based on a script used in a study by Dworkin et al's on influencing the effects of nitrous oxide by means of information (Dworkin et al., 1984). See chapter 1 and Appendix 3 This describes the effects of nitrous oxide as follows:

"One way that nitrous oxide works is as a sedative or tranquiliser. It lowers the brain's level of consciousness about anxiety and pain, making people feel good. The first signs that nitrous oxide is changing how your brain is processing information comes from changes you can readily experience with lower doses of nitrous oxide – your toes, maybe your fingers may begin tingling and a kind of warm glow may come over you; a feeling of relaxation of muscle tension. This feeling of relaxation helps to reduce anxiety levels and generally feels very pleasant."

The information sheet for the hypnosis group included identical information

about nitrous oxide and sedation, but also contained an explanation of hypnosis,

including side effects and risks which was informed by the report produced by

the British Psychological Association 'The nature of Hypnosis' (Heap et al,

2001). This sheet described the hypnosis as:

"A hypnotic 'induction' which will give suggestions for relaxation and for becoming absorbed in your inner experiences such as feelings, thoughts and imagery. This will be followed by suggestions for calmness, relaxation and wellbeing to continue after the hypnosis. Most people find hypnosis to be a pleasant experience."

(Full text in Appendix 4)

The reason for not informing all participants of the inclusion of hypnosis as one of the test conditions was to avoid the possibility of a 'hold-back effect'. This is a well-known phenomenon in hypnosis research whereby participants' beliefs about hypnosis cause them to hold back their responses in non-hypnosis conditions, due to the expectation that hypnosis will have more effect than nonhypnotic conditions (Rainville, 2008, Braffman and Kirsch, 1999).

### Equipment

The sedation equipment used was a Quantiflex MDM dedicated Inhalation Sedation machine with a single mask system. This has the following safety features built in:

- 1. A maximum nitrous oxide concentration of 70% and minimum oxygen concentration of 30%.
- 2. Automatic cut-off of the flow of nitrous oxide should the oxygen flow cease.
- Two oxygen cylinders and two nitrous oxide cylinders should one fail or run out.
- 4. A pin system which prevents the wrong cylinder being attached.
- 5. Active scavenging of waste gases.
- 6. Autoclavable masks and disposable tubing.

Two lap-top computers were also used, one with the audio CDs inserted according to the randomisation of the participants and one with a video CD of the film clip.

## Audio CDs

Two audio CDs were produced, one for the hypnosis group and one for the control group. Recordings were chosen rather than live presentations as this ensured standardisation throughout the experiment, including equal time and control over possible confounding factors such as changes in voice tone or nonverbal cues from the experimenter. It also facilitated the blinding of the experimenter as the CDs were loaded by the dental nurse who monitored the participant during sedation, but was otherwise uninvolved in the experiment. A little evidence suggests that standardised recorded hypnosis is not as effective in reducing anxiety as 'live' hypnosis with individualised imagery suggestions (Ghoneim et al., 2000, Wannemueller et al., 2011, Shenfelt, 2013), although the evidence for this is weak. Tape recorded hypnosis has also been shown to be effective in some studies (see chapter 2) (Ghoneim et al., 2000, Eitner et al., 2011, Eitner et al., 2006b, Enqvist and Fischer, 1997, Enqvist et al., 1995a, Enqvist et al., 1995b).

The control audio recording was the principle investigator reading an excerpt from the first book, of the Gormenghast trilogy – The House of Groan by Mervyn Peak (Peake, 1992) p7-13. The recording lasted 26 minutes. This excerpt was carefully chosen as it does not have content which aims to produce strong emotion in the reader. It contains a description of a castle and a room with an exhibition of carvings together with an interaction between two characters about the birth of a child. The story was read with appropriate voice inflexion and the book was named at the end of the recording. The hypnosis recording was the same length and consisted of a relaxation induction procedure which asks the participant to concentrate on their breathing, noticing the relaxation produced on the out-breath. This was followed by a progressive muscular relaxation sequence from the head to the feet (Simons et al., 2007). This is a commonly taught and widely used hypnotic induction procedure. It ends with a permissive suggestion for eyelid catalepsy – "The muscles of your eyes and your eyelids are so heavy, so relaxed and so comfortable that even if you wanted to, it would be far too much trouble to open them"

The induction was followed by a deepening procedure comprising a combination of a counting with imagery process and the 'Special place' suggestion. This consisted of suggestions that the participant imagine standing at the top of a flight of twenty stairs leading down to a special place that could be anywhere they wanted. The steps are then descended to a count of one to twenty, with each step becoming more and more deeply hypnotised until the special place is reached when they can just enjoy being there. Special place imagery has the advantage that suggestions can be very general in nature and is successful even when the therapist does not know what the person is imagining. Suggestions are given to imagine the place in detail, for example "look all around your special place and notice everything you can see, hear all the sounds you can hear" and so on (Simons et al., 2007). This process was around 13 minutes long. This was followed by continual suggestions of calmness, control over anxiety and relaxation with direct suggestions for remaining calm and nonanxious whilst watching the film – "And in a moment, I'm going to ask you to open your eyes and I'm going to ask you to watch a film, which in the past might have bothered you, but now, you can stay completely calm, completely comfortable and completely relaxed." The suggestions for remaining calm

whilst watching the film were intended to function as a post-hypnotic suggestion, that is, a suggestion given in hypnosis intended to take effect after the termination of hypnosis (Simons et al., 2007). Post-hypnotic suggestion was chosen to make it easier for the patient to concentrate on the film whilst it was being shown and also because it was simpler to run the experiment in this way. This technique is useful clinically, as the response to such a suggestion is experienced as automatic and persists for some time (at least for highly hypnotisable participants) (Barnier and McConkey, 1998). This has been challenged in other studies where participants have been shown not to respond outside the experimental setting (Spanos et al., 1987). This should not be a problem in this study as the response is requested during the experiment. The participant was then aroused from hypnosis using a count-down from five to one.

The script was developed by recording with a live volunteer in order to make the hypnosis as natural as possible. This recording was transcribed, edited and re-recorded to produce the CD for the experiment. (full text is provided in appendix 4)

## Anxiety Stimulus

The video used for the second study (described in chapter 3) was used in this experiment; as before it lasted 4 minutes 50 seconds.

#### Procedure

Volunteers were recruited using the University of Manchester online recruitment system. When an email was received from a potential volunteer they were sent a file containing the first information sheet, a consent form, medical history form, MDAS questionnaire and STAI(T) questionnaire; they were asked to complete the forms and return the file by email. (appendix 3). The forms were then checked for completeness and to determine the individual's medical status and MDAS score.

Participants with unsuitable medical histories or MDAS scores indicating dental phobia were excluded and emailed thanking them for their interest and explaining their exclusion from the study. The rest were passed to a research assistant (a trained dental nurse) who was blind to the questionnaire results. The research assistant randomised the participants by using sealed opaque envelopes containing cards for group A or B. Following randomisation, the appropriate second information sheet was emailed by the research assistant to the participant with a reassurance that they could withdraw at this stage if they wished. Participants were asked to contact the dental nurse if they needed further information and the contact details of one of the research supervisors (RB experienced in hypnosis) if further details were needed specifically about hypnosis. This was to maintain the blinding of the main experimenter. The study ran between November 2007 and June 2008.

On arrival for the experiment, participants' medical histories were checked for changes and they had the opportunity to re-read the information leaflets before

the procedure was explained and they consented to the experiment by signing the consent form. To preserve blinding of the experimenter, the initial stages were carried out by the same dental nurse who had randomised the participant. The experimenter entered the surgery only to check understanding, allow further questions and to gain informed consent, witness and countersign the consent form.

The procedure was standardised for all participants. The anxiety scale was explained as "a simple numerical scale from one to one hundred where one is as relaxed and non-anxious as you can ever imagine being and one hundred is as anxious as you can ever imagine being." Measures were taken before the experiment started (time point 1), after the level of nitrous oxide sedation had been established (time point 2), after the intervention (time point 3), after the film (time point 4) and at the end of the experiment, following recovery from sedation (time point 5). The measures were requested verbally by the experimenter, who was blind to the group (hypnosis or story) of the participant. Nitrous oxide sedation was administered according to a standard clinical protocol. Two appropriately trained clinicians were present for the entire session as is recommended for conscious sedation. The experimenter administered the IHS and along with the Dental Nurse, monitored the patient. The participant breathed oxygen until an appropriate flow rate was obtained. Nitrous oxide was then introduced gradually as follows, with the comfort and sensations of the participant checked between each stage:

• 10% nitrous oxide/90% oxygen for two minutes

- 20% nitrous oxide/80% oxygen for two minutes
- If no changes in sensation were reported, nitrous oxide increased in 5% increments with two minutes between each increment.

Once the participant reported a comfortable level of sedation as evidenced by feelings of relaxation and/or tingling sensations in the extremities, the participant's anxiety level at time point 2 was taken.

Headphones were then placed and the participant listened to the appropriate CD recording on the laptop. The CD was placed in the laptop by the research assistant to preserve the blinding of the experimenter. Once the recording had finished, the participant's anxiety level at time point 3 was taken. The headphones were then plugged into a second laptop on which the film

DVD was shown, after which the participant's anxiety level at time point 4 was taken.

Participants then breathed pure oxygen for at least two minutes to prevent diffusion hypoxia, with the experimenter checking that they were back to normal before removing the nose piece. The final anxiety scale measure (time point 5) was then taken.

Care was taken to check that participants had fully recovered before they left the dental hospital using standard clinical protocols for adult IHS.

# **Hypotheses**

 The null hypothesis is that there will be no difference in the changes of reported anxiety between the groups.

- 2. The alternative hypothesis is that the group receiving hypnosis alongside the nitrous oxide inhalation sedation will show a smaller increase in reported anxiety levels after watching the film than the group receiving the control story alongside the nitrous oxide inhalation sedation.
- 3. There will be a correlation between MDAS scores and the benefit from the hypnosis intervention.

## Statistical Analysis

Results were analysed using the statistical package SPSS for windows v.13. If the data were normally distributed it was planned to use analysis of covariance (ANCOVA) to analyse the results as recommended by Vickers and Altman (2001). Should the assumptions for the use of parametric methods be violated, non-parametric methods would be used instead. This would entail the calculation of change scores between the various time points of the experiment. Effect sizes for the interventions and for the film would also be calculated.

#### Sample size calculation

A sample size calculation was carried out using the results from the second experiment (Chapter 3). Means and SDs of the changes in anxiety levels produced by the film were used in the power analysis program G\*Power 3 (Faul et al., 2007). This program allows the calculation of sample sizes when an estimate of the differences between groups can be made. It uses the required power level and significance level and the effect size to be detected to calculate sample size.

The assumptions were that the IHS alone would reduce the anxiety produced by the film and that hypnosis would reduce it even further. The power level was set at 0.8 and the  $\alpha$  error probability was set at 0.05 as is conventional. The mean increase in anxiety produced by the film in study 2 (chapter 3) was 37.77 (SD 24.42) when calculated from the low anxiety point at the end of the experiment. It was assumed that IHS would produce 10 points reduction on the 1-100 scale and that the addition of hypnosis to this would produce a further 20 points reduction; using these figures, the calculation indicated that a sample size of 28 participants per group would be needed to have 80% power to show a significant difference between the groups. This is a conservative estimate, as the distribution of the sample is not assumed to be normal in this calculation. These figures are estimates of the effects that we are looking for, but this is supported by the sample used in a study which compared the effects of differing information provision in reducing anxiety in oral surgery patients (Ng et al., 2004). In this study samples of between twenty three and twenty five patients were sufficient to show significant differences between four groups on a 0-100 SUDs scale measured over seven time points and averaged to give an overall anxiety score.

The total sample size was chosen as 60 (30 participants in each group) to allow for drop-outs.

## Results

One hundred and eight individuals returned the medical history form, MDAS and STAI(T). Of these, forty five attended for the study, two of whom withdrew during the procedure due to nausea on breathing the nitrous oxide. Thirty three people were invited but did not attend, usually due to time commitments. Three participants were excluded due to high scores on the MDAS scale which indicated possible dental phobia. Three were excluded for other reasons (one due to complex medical problems and two due to missing data that they failed to supply despite being reminded). The excluded participants were not randomised. The invited but did not attend group were randomised (17 to the story group, 16 to the hypnosis group). Following their failure to attend, their group cards were re-sealed in further opaque envelopes to be re-drawn for further participants.

Following an interim analysis of the data indicating no effect of the intervention, a decision was made to end the study prematurely. Twenty four people were therefore not invited to participate or randomised. These participants were sent an email to thank them for their interest and inform them that the study had now ended. Descriptive statistics for the groups are given in Table 42

N	Group	Age		Gender	MDA	S	STAL	Γ
		Mean(SD)	Range		Mean(SD)	Range	Mean(SD)	Range
43	Attended and completed	21.58(3.34)	18-31	F- 26 (60.5%) M-17 (39.5%)	10.5(3.06)	5-17	42.09(10.35)	24-64
2	Withdrew at appointment	19(1.41)	18-20	F-2 (100%)	13(7.07)	8-18	33.5(0.71)	33-34
33	Invited but did not attend	21.97(3.39)	18-32	F – 17 (51.5%) M – 16 (48.5%)	9.82(3.31)	5-17	36.34(7.19)	25-58
3	Excluded dental phobia	19.33(2.30)	18-22	F - 1 M -2	20.33(5.77)	20-21	36.67(8.02)	29-45
3	Excluded other	20.33(1.53)	19-22	F -1 M - 2	15.33(2.08)	13-17	Not computed – missing values	
24	Not invited	22.46(4.26)	18-35	F -10 (41.7%) M - 14 (58.3%)	10.5(3.09)	6-17	36.41(6.98)	26-49

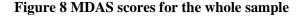
# Table 42 Descriptive statistics for volunteers in the experiment

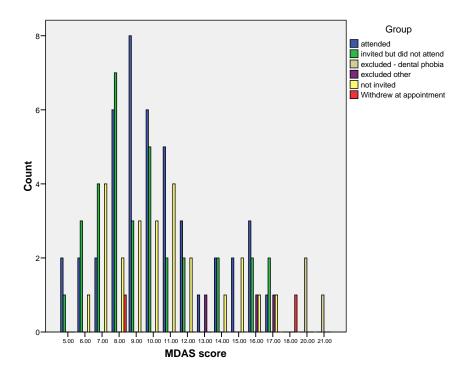
# Figure 7 Flow chart of phases of the experiment

<b>Recruited online</b>	n=108
Not invited or randomised	n=24
Excluded	
Dental phobia	n=3
Other	n=3
Invited to attend	n=78
DNA	n=33
Attended	n=45
Randomised story	n=23
Randomised hyp	n=22
Withdrawn at appointment	n=2
Analysed	n=43
Story	n=23
Hypnosis	n=20

MDAS scores for the whole sample are shown in figure 8 which shows a distribution that is skewed significantly towards the lower values (z(skewness) = 0.794/0.233 = 3.408 p < 0.01). Transformations of the data did not result in a normal distribution, therefore non parametric statistics will be used for analysis of this data. This is true also of the STAI(T) scores (z(skewness) = 0.525/0.236=2.224 p < 0.05).

There were no significant differences between any of the groups on age or STAI(T) scores using the Kruskal Wallis test.





For MDAS scores there was a significant difference when comparing all the groups on the Kruskal Wallis test (Chi – Square 15.582 df5 p=.008). Post-hoc Mann-Whitney tests revealed that the 'attended' group did not differ from any other groups except the group that was excluded due to dental phobia (U=.000,

p=.004 (2-tailed)). This group also differed significantly from the groups 'not invited' and 'invited but did not attend'.

No other differences were found between groups. There was no significant correlation between scores on the STAIT(T) and the MDAS scales.

#### Main analyses

Forty three participants completed the experiment, see table 43 for demographic characteristics. Two participants withdrew during the intervention stage and their data were excluded from the analysis. Both of these participants complained of some dizziness and slight nausea. One of these participants reported often suffering from motion sickness and felt the symptoms were similar. The other had no predisposing factors, but continued to feel slightly nauseous even when the concentration of nitrous oxide was reduced from 25% to 20%. For both participants it was decided to end the experiment to allow recovery. Both were recovered using 100% oxygen and had no further problems. Both participants had been randomised to the hypnosis group. Twenty three participants completed the study in the story group and twenty in the hypnosis group. There were no significant differences between the two groups on age, gender, MDAS or STAIT scores.

#### Table 43 Demographic details of participants

Measure	Mean(SD) story group (n=23)	Mean(SD) hypnosis group (n=20	Significance p=
Age	21.35(3.084	21.13(3.675)	.629
Gender numbers in	15F 8M	11F 9M	.545
each group			
MDAS	10.52(2.71)	10.05(3.47)	.620
STAI(T)	41.74(9.89)	42.5(11.09)	.813

## Nitrous Oxide Administration

The maximum percentage of nitrous oxide administered during the study was not significantly different U=211.5 p=.567 between the groups (median 25 for both groups). The majority of participants – 31 (15 in the story group, 16 in the hypnosis group received 25% nitrous oxide 75% oxygen, 3 participants received 20% nitrous oxide (2 in the story group one in the hypnosis group), 8 received 30% nitrous oxide (3 in the hypnosis group the remainder in the story group) and one, 40% (story group).

## Anxiety ratings over time

Exploration of these data revealed non-normal distributions, confirmed by the Kolmogorov-Smirnov and Shapiro-Wilk tests. Transformations of the data did not correct this. For this reason, and also as the groups are unequal in size, nonparametric analysis were used.

Descriptive statistics are shown in table 44.

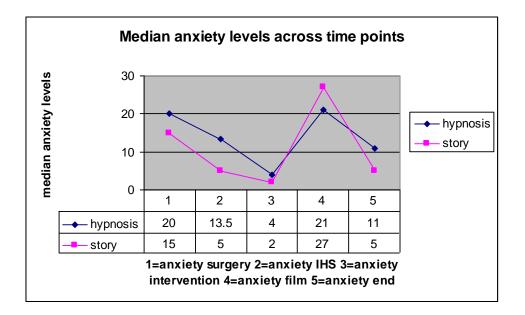
hypnosis or story		Anxiety score surgery (time point 1)	Anxiety score nitrous oxide (time point 2)	Anxiety score intervention (time point 3)	Anxiety score film (time point 4)	Anxiety score end (time point 5)
Story n=23	Median	15.0000	5.0000	2.0000	27.0000	5.0000
	Inter Quartile Range	20	11	9	41	15
	Range	59.00	32.00	29.00	79.00	39.00
Hypnosis n=20	Median	20.0000	13.5000	4.0000	21.0000	11.0000
	Inter Quartile Range	28.75	13.75	5.5	69	14.25
	Range	59.00	74.00	9.00	69.00	34.00

Table 44 Descriptive Statistics for Anxiety Levels over time for each Group

Two measures of anxiety were taken which could be considered as baseline measures. One was at the beginning when the participants entered the dental surgery (time point 1) and one at the end when they were recovered and ready to leave (time point 5). The groups did not differ on either of these occasions. Anxiety time point 1 – hypnosis group median anxiety = 20, story (control group) median anxiety = 13 Mann-Whitney test U=172.5 ns, anxiety at the end hypnosis group median anxiety = 11, story (control) median anxiety = 5 U=201 ns. However, for the whole sample their anxiety scores at the end of the experiment were significantly lower than at the start (start median = 20, end median = 10) Wilcoxon signed ranks test T = 10.5 p< .000. Anxiety scores were compared (Mann-Whitney test) at all five time periods, there was no significant difference between the groups at any of the time points,

whilst there were significant differences in anxiety scores across time for both groups.

The anxiety levels were significantly lower between time point 1 (mdn = 20) and time point 2 (mdn = 10) (Wilcoxon signed ranks test T = 55 p< .000), were again significantly lower at time point 3 (mdn 3) (Wilcoxon signed ranks test T = 20 p< .000) then significantly higher at time point 4 (mdn 22) (Wilcoxon signed ranks test T = 1.5 p< .000). Anxiety levels were significantly lower at time point 5 (mdn = 10) (Wilcoxon signed ranks test T = 43 p< .000), interestingly, this level of anxiety is not significantly different than the level seen after the administration of nitrous oxide (T = 227.5 ns).



#### Figure 9 median anxiety levels across time points

## Change scores

Descriptive statistics for anxiety change scores are given in table 45

 Table 45 Descriptive statistics for the changes in anxiety through the experiment

	Statistic	Hypnosis	Story
Difference in anxiety scores between	Median	-9.5	-9
time point 1 and time point 2	Interquartile Range	22.5	11
Difference in anxiety scores between	Median	-9.5*	-4*
time point 2 and time point 3	Interquartile Range	10.5	5
Difference in anxiety scores between	Median	17.5	14
time point 3 and time point 4	Interquartile Range	41	46
Difference in anxiety scores between	Median	-7.5	-7
time point 4 and time point 5	Interquartile Range	30.75	44
Difference in anxiety scores between	Median	-6**	3**
time point 4 and time point 1	Interquartile Range	31.25	23

(\*- significant difference p=.002 \*\*- significant difference p=.028)

The distributions of these data were significantly non-normal as shown by significant results of the Kolmogarov-Smirnov tests. Transformations were unsuccessful in correcting this. Accordingly they were analysed using non-parametric statistics.

Hypnosis produced a significantly greater reduction in anxiety than the story (change from time 2 to time 3; U=357.5 p=.002). However, there was no between group difference in change scores from before to after the film (time 3 to time 4. (U = 217 p+.751).

#### Analysis of the groups separately

In experiment 2 the effect size for the film was calculated from the change in anxiety levels from in the surgery to after watching the film. The equivalent times in this experiment are time 1 and time 4. When groups were analysed separately, comparing these time points, there was no significant difference between the scores in the hypnosis group ( time point 1 Mdn=20 and time point 4 Mdn=21) T=98.5 z=.567 ns, but there was a significant difference in the story

group, time point 1 Mdn=15, time point 4 Mdn=27 T=54 z=-2.141 p=.032 (related samples Wilcoxon Signed Rank Test).

Using these results to calculate separate estimated effect sizes for the film in each group reveals a very small effect size for the film in the hypnosis group of 0.09 and a larger, but only medium effect size for the film in the story group of 0.32.

However, using time point 5 as the baseline, there was a significant difference in both groups. Hypnosis group (time point 5 Mdn 11, time point 4 Mdn 21) T = 18 z = -2.774 p = .006. Story group (time point 5 Mdn 5, time point 4 Mdn 27) T = 2 z = -3.848 p = .000 (related samples Wilcoxon Signed Rank Test). These results give effect sizes for the hypnosis group of 0.44 and the story group of 0.55, a medium to large effect in the hypnosis group and a large effect in the story group (Field, 2005).

In addition, if the effect size for the film is calculated using the same method but the starting point is time point 3 (after the intervention) the film produced a large increase in anxiety (ES=0.82 for both groups).

## **Correlations**

MDAS scores correlated significantly with anxiety levels at time 4 in the story group (Spearman's Rho = .417 p=.048), but not in the hypnosis group (Spearman's Rho = .145 p=.542),

MDAS scores also correlated significantly with the change in anxiety time 1 to time 4 and time 3 to time 4 in the story group (Spearman's Rho=.459 p=.028

and Spearman's Rho = .506 p=.014), but not in the hypnosis group (Spearman's Rho=.142 p=.550 and Spearman's Rho = .1 p=.676),

#### Discussion

This study shows that during each stage of the experiment, there seems to be no difference between the group who received nitrous oxide sedation combined with a story and the group who received IHS combined with hypnosis in terms of self-reported anxiety. The study was halted before the full 30 participants in each group has been recruited because an interim analysis showed that no significant differences were likely to be shown by running further participants. Both interventions produced large falls in anxiety levels compared to the beginning and ends of the experiment, and participants left significantly less anxious than when they arrived. The induction of nitrous oxide sedation alone removed any anticipatory anxiety that participants reported, the anxiety levels at the end of the experiment being very similar to those after the introduction to nitrous oxide.

Hypnosis produced a greater fall in anxiety levels than the story immediately after the procedures, but this difference did not continue when participants watched the film, with both groups becoming comparably anxious after watching it. This suggests that the hypnosis intervention did not have a greater anxiety-buffering effect than the story control, contrary to prediction. The calculation of change scores indicated that, although there was no significant difference in the self-reported anxiety between the groups at the start of the experiment or after watching the film, the change between the two times

was statistically significant with the story group showing a median increase in anxiety (Mdn=3) and the hypnosis group showing a median decrease (Mdn=-6). However, the variability in scores for both groups was high. The clinical significance of this difference is therefore uncertain at best.

Participants MDAS scores correlated with the anxiety produced by the film in the story group, but not in the hypnosis group. MDAS scores also correlated significantly with the increase in anxiety produced by the film in the story group, but not in the hypnosis group suggesting that participants with higher dental anxiety on the MDAS scale may benefit more from the hypnosis intervention.

#### **Methodological Issues**

#### The SUDs Scale

Although SUDs scales have been used successfully in previous research (Ng et al., 2004) in this experiment the scale may have been problematic. Most participants reported low levels of anxiety to start with, which made later measures difficult as there was insufficient space at the lower end of the scale. Some participants asked if they could report negative values, particularly after the intervention. They also had difficulty in deciding how anxious they normally were.

In addition, there seemed to be confusion between anxiety and relaxation which may be a result of the instructions given to the participants ("a simple numerical scale from one to one hundred where one is as relaxed and non-anxious as you can ever imagine being and one hundred is as anxious as you can ever imagine being.")

#### Deciding on Baseline Anxiety

Two time points could be used as baseline in this experiment – time point 1 or time point 5. It has been argued that following informed consent procedures, anticipatory anxiety will be produced, making measurements of baseline at the start inaccurate (Farha and Sher, 1989). In this experiment, the alternative of taking a baseline measure at the end is also potentially problematic, as the suggestions given in hypnosis included general anti-anxiety instruction, for example,

"And any time that anyone or anything tries to bother you or disturb you, you'll just find that you think to yourself of your special place and the words Calm, Comfortable and Completely relaxed, and the disturbance and the anxiety and the worry will just disappear" (Appendix 4)

These suggestions could be responsible for the lower anxiety levels at the end of the experiment in the hypnosis group, although the story group showed corresponding reductions so this may be a legitimate baseline measure. Effect sizes for the film were therefore calculated using both possible baselines. Using the anxiety levels at the end of the experiment gave more equal effect sizes and so is probably more realistic than the alternative.

#### Blinding of the Experimenter

Blinding was breached for almost all participants as the appearance of those in the hypnosis group was very different than those in the story group. The hypnotised individuals appeared much more relaxed, less alert and almost always had their eyes closed. This is a potential source of bias, as the experimenter was interacting with the participants during the experiment.

#### Hypnosis Method

Another explanation of the apparent equivalence of the story and the hypnosis may be due to the hypnotic technique. The use of hypnosis produced a large reduction in anxiety levels over and above the effect of the IHS (ES r=0.59) and there was a statistically significant difference between the groups' median decrease in anxiety when change scores were calculated. However, reading the story also produced a reduction in anxiety, with only a slightly smaller effect size (ES r=0.46).

In addition, the increase in anxiety produced by the film (after the end of the intervention to after watching the film) was not significantly different between groups. This may be a failure of participants in the hypnosis group to respond to the post-hypnotic suggestion. Most hypnosis research is carried out on pre-selected, highly hypnotisable individuals and research on post-hypnotic responding is no exception. It may be that PHS is not a strong enough phenomenon in unselected groups. An alternative way to use hypnosis clinically is for a patient to remain in hypnosis for their dental treatment, with

the dentist continuing to give suggestions of relaxation and comfort throughout (Simons et al., 2007).

#### The Control Recording

Although the recording was not emotional, it is very descriptive. This may have led to control participants being absorbed in imagery, which although not *hypnosis* is certainly *hypnotic*. Imaginative ability has been shown to be increased by inhalation sedation (Whalley and Brooks, 2009). In addition, absorption has been proposed as a way to facilitate anxiety reduction in psychotherapy (Bowins, 2012). These mechanisms may account for the lower anxiety scores after the intervention in the control condition. Alternatively, this may simply be a result of breathing nitrous oxide for a longer time, although both groups had the same length of time under IHS.

## **Conclusions**

Although the experiment failed to show the hypothesised differences between IHS plus hypnosis and IHS plus a control story, there are indications that this may be due to the methodological issues identified above. A second experiment was designed to correct these.

# **Experiment 2**

# Introduction

This experiment was designed to improve on experiment 1 by addressing the methodological issues discussed above. A substantial amendment was approved

by COREC on 24<sup>th</sup> February 2009. The study ran between August 2009 and March 2010.

#### **Methods**

#### Design

Similar to experiment 1, this experiment used a between subjects, repeated measures design. There were two dependent variables: self-reported anxiety and self-reported relaxation. As before, the within subjects variable was time, which had five levels: (time 1 [sitting in the dental surgery] vs. time 2 [after a physiologically and psychologically comfortable level of sedation was reached] vs. time 3 [after listening to the story or hypnosis], vs. time 4 [after watching the film] vs. time 5 [at the end of the experiment]). The between subjects independent variable was condition, which had two levels: control [IHS plus a story] versus intervention [IHS plus hypnosis].

#### Setting

This was identical to experiment 1

## **Participants**

Participants were recruited in the same way as experiment 1 and, in addition, volunteers who were not invited for experiment 1 were contacted by email and asked if they wished to participate. They were reimbursed £10 for inconvenience and travel.

Inclusion and exclusion criteria were identical to experiment 1.

#### **Materials**

The questionnaires and information sheets were the same as experiment 1. Two new CDs were prepared so separate audio and video CDs were not needed. They included recordings of the story intervention and the hypnosis intervention followed by the film. They also incorporated requests for anxiety and relaxation measures (described below) which removed the need for any interaction between the experimenter and the participant once a comfortable level of sedation had been reached.

A major difference in the hypnosis version was that the participant was explicitly instructed to remain in hypnosis whilst watching the film. Full text is in appendix 4.

"Now relaxing deeper and deeper into hypnosis with your eyes open I'm going to show you a film. You can stay deeply relaxed and deeply hypnotised whilst you watch the film. Nothing that you see or hear needs to bother or disturb you in any way you can stay completely calm completely comfortable and completely relaxed. Nothing needs to bother you or disturb you nothing needs to make you anxious. Anything that bothers you can just drift away into the background and you can stay just as calm, just as relaxed and just as comfortable as you are right now. You can concentrate on listening to the sound of my voice or drift back to your special place all the time feeling calm, comfortable and completely relaxed."

During the film, the hypnosis group heard continuous suggestions to remain

calm and relaxed, not letting the film bother them at all.

The story group heard the story continuing to be read alongside the film clip

which was explained on the CD:

"Now, keeping your eyes open, I'm going to ask you to watch the film. I'll keep reading the story whilst you do so." They were also asked in the recordings to give measures of anxiety and

relaxation (see below)

## Measures

The measures used were identical to the previous experiment with the exception of redesigned scales to record anxiety and relaxation during the experiment. They were explained to participants using the same verbalisation for every participant:

I will ask you for scores on scales for anxiety and relaxation. The scales will go from minus 50 to plus 50. Zero is how you normally feel. "For the anxiety scale: Zero is how you normally feel, plus 50 is as anxious as you can ever imagine being and minus 50 is as non-anxious as you can imagine being. For the relaxation scale: zero is how you normally feel, 50 is as nonrelaxed or tense as you can imagine ever being, and minus 50 is as

relaxed as you can ever ever feel that you might be."

These scales aimed to make it easier for participants to decide how anxious or

relaxed they were at various points during the experiment by giving a starting

point of zero being how they normally feel.

During the session requests for scale measures were given on the CD

recordings to avoid interactions between the experimenter and participant. For

example, the story group received the following instructions before watching

the film:

"Ok. I'm going to stop reading the story for a moment. If your eyes are closed, please open them now. Now, please give me a number on the scale for anxiety, remember that zero is how you normally feel, 50 is as anxious as you can imagine ever being and minus 50 is as non-anxious as you can imagine ever being.

Give me a number now and I will write it down.

*Ok, now please give me a number on the scale for relaxation. Remember that 0 is how relaxed you normally feel, 50 is as non-relaxed or as tense as you can imagine being and -50 is as relaxed as you can ever ever feel that you might be. Give me a number now and I'll write it down.*" Pauses were left to allow the participant to respond to the requests. No participants had difficulty in complying with the requests during the experiment.

#### Procedure

Participants were recruited and screened as for the previous study. Those who attended for the experiment, completed the anxiety scale and relaxation scale in the dental surgery whilst seated comfortably in the dental chair (time point 1). The chair was semi-reclined and the IHS nasal hood was placed on the nose ensuring there were no leaks. The experimenter titrated the nitrous oxide in the same way as experiment 1 until the participant reported feeling comfortable and relaxed with no disorientation or nausea. They then completed the two scales as before (time point 2).

The participant was then played (through headphones) one of 2 audio recordings (as previously described). Each recording lasted about 30 minutes. Following the end of the recordings participants in the hypnosis group remained in hypnosis and completed the two scales again. The story group also completed the scales (time point 3).

Both groups then watched the film clip. The nitrous oxide/oxygen mixture remained flowing. During the film, the hypnosis group continued to receive suggestions appropriate to reduce anxiety from the sights and sounds of the film as described above. The story group continued to hear the story being read over the soundtrack of the film. Following the end of the film both groups completed the two scales (time point 4). They were asked to give a number corresponding to "how watching the film made you feel".

Following the completion of the scales, hypnosis group participants were told that all bodily sensations will shortly return to normal and they were dehypnotised using the same procedure as experiment 1.

Both groups were informed that following two minutes' administration of 100% oxygen they would be fully alert and rested. Two minutes of pure oxygen was administered and the experimenter checked that the participant was fully alert and awake and that their bodily sensations had returned to normal before disconnecting the IHS machine and moving the chair into the upright position. Participants completed the scales again once fully recovered (time point 5). Participants rested for 30 minutes before being allowed to leave. They had the opportunity to discuss their experience and report any problems they felt and were provided with a telephone and email contact in case of any later effects from the experiment. This was not used by any of the participants.

#### Analysis

Results were analysed using IBM SPSS Statistics 20 with the same assumptions, aims and statistical tests as experiment 1.

## Results

#### **Participants**

Overall 96 participants completed the questionnaires and volunteered for the experiment. Of these, 55 attended, 20 did not attend when sent an appointment,

three were excluded as their MDAS scores indicated they were highly anxious about dentistry (scoring over 19 on the MDAS), three were excluded for other reasons (one was a 4<sup>th</sup> year dental student, one had a complex medical history and one was breast feeding) and 15 withdrew before their appointments. All but one withdrew because they were unable to attend appointments. One person withdrew as they did not want hypnosis.

In this study, no participants withdrew at the appointment.

#### Figure 10 Flow chart of phases of the experiment

<b>Recruited online</b>	n=96
Excluded	
Dental phobia	n=3
Other	n=3
Invited to attend	n=90
Withdrawn before appt	n=15
DNA	n=20
Attended	n=55
<b>Randomised story</b>	n=26
<b>Randomised hyp</b>	n=29
Analysed	n=55
Story	n=26
Hypnosis	n=29

Descriptive statistics for the groups are given below in table 46.

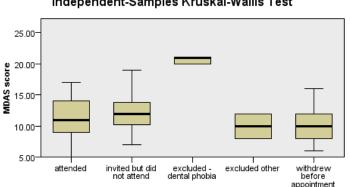
Group	Gen	ıder	Age in y	ears	MDAS s	core	STAI(T)	score	N
	М	F	median	Interquartile range	median	Interquartile range	median	Interquartile range	
Attended	24	31	22	4	11	5	38	13	55
Invited but did not attend	10	10	22	3	12	3	34	18	20* (valid N=19)
Excluded (high dental anxiety	3	0	21	-	21	-	40	-	3
Excluded (other)	0	3	23	-	10	-	40	-	3
Withdrawn before appointment	4	11	23	5	10	4	43	19	15

**Table 46 Descriptive statistics for volunteers** 

\*this difference is due to missing values of one participant. Non parametric statistics are reported due to the unequal group sizes

Independent Samples Kruskal-Wallis tests show that the groups did not differ significantly on the distribution of STAI(T) scores or age, but did differ on MDAS scores (H(4) = 13.355 p = .010). Examination of the boxplot of these scores shows that this difference is due to the three volunteers who were excluded due to high dental anxiety (possible phobia) (figure 7).

Figure 11 Boxplot of anxiety levels of groups of volunteers



Independent-Samples Kruskal-Wallis Test

Subsequent analyses were confined to the 55 participants who attended.

Independent Samples Mann-Whitney U tests reveal that the groups did not vary in MDAS scores, STAI(T) scores or age.

Group	Gende r		8 2		MDAS score		STAI(T) score		N
	Μ	F	media	Interquartil	media	Interquartil	media	Interquartil	
			n	e range	n	e range	n	e range	
Hypnosi	1	1	22	3	11	5.5	38	14.5	2
s	3	6							9
Story	1	1	24	5.25	10	5	39	10.75	2
-	5	1							6

# Nitrous Oxide Administration

The percentage of nitrous oxide delivered to each group was not significantly different; the median for both groups was 25% (story group maximum 30% minimum 20%, hypnosis group maximum 40% minimum 15%). Exact frequencies are given below in table 48.

## Table 48 maximum percentage of nitrous oxide given to participants

Nitrous oxide percentage	10%	15%	20%	25%	30%	35%	40%
Hypnosis	0	1	5	16	6	0	1
Story	0	0	4	18	4	0	0

# Anxiety levels over time

The majority of these data were non-normally distributed shown by positive results of the Kolmogorov –Smirnov and Shapiro-Wilk tests. Results for the Kolmogorov-Smirnov tests are given below in table 49.

<b>Table 49 Normality</b>	v tests for	anxiety levels
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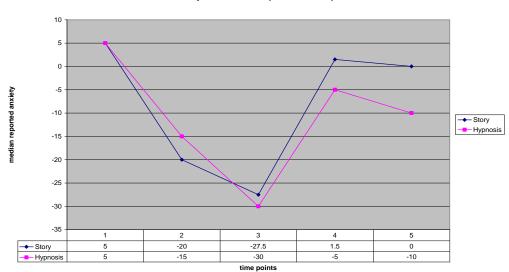
	Story or Hypnosis	Kolmogorov-Smirnov test			
		Statistic (D)	df	significance	
Time point 1	Story	.225	26	.002	
	Hypnosis	.225	29	.001	
Time point 2	Story	.164	26	.070	
	Hypnosis	.121	29	.200	
Time point 3	Story	.171	26	.048	
	Hypnosis	.167	29	037	
Time point 4	Story	.101	26	.200	
	Hypnosis	.103	29	.200	
Time point 5	Story	.286	26	.000	
	Hypnosis	.216	29	.001	

Transformations of the data did not correct this and also the groups were unequal in size. Accordingly, non-parametric analyses were used. Descriptive statistics are shown below in table 50.

Hypnosis or story		Anxiety score surgery (time point 1)	Anxiety score nitrous oxide (time point 2)	Anxiety score intervention (time point 3	Anxiety score film (time point 4)	Anxiety score end (time point 5)
Story	Median Interquartile range	5 7	-20 30	-27.5 38.5	1.5 40	0 10
Hypnosis	Median Interquartile range	5 10	-15 22.5	-30 17.5	-5 37.5	-10 30

Table 50 median levels of self-reported anxiety at five time-points

### Figure 12 Median anxiety levels at five time points of the experiment



Median Anxiety Levels at 5 time-points of the experiment

#### **Change Scores**

Changes in anxiety scores between the different time points were calculated by subtracting the scores; time point 1 to time point 2, time point 2 to time point 3 and so on.

No significant differences were found between the groups for any change in anxiety levels, when time points were considered in chronological order, except for the change (reduction) in anxiety between time-point 2 and time-point 3 (median change in anxiety levels: hypnosis group = -20, story group = -7.5 U = 548 z = -2.905 p = .004). Also, the hypnosis group changed (reduced) anxiety levels significantly more than the story group between when they arrived and the end of the experiment (median change in anxiety levels: hypnosis group = -15 story group = -8, U = 223 z = -2.62 p = .009).

 Table 51 Median Change scores

	Statistic	Hypnosis	Story
Difference in anxiety scores between	Median	-20	-25
time point 1 and time point 2	Interquartile Range	15	25
Difference in anxiety scores between	Median	-40*	-32.5*
time point 2 and time point 3	Interquartile Range	17.5	34.25
Difference in anxiety scores between	Median	20	19.5
time point 3 and time point 4	Interquartile Range	35	31.25
Difference in anxiety scores between	Median	-5	-7.5
time point 4 and time point 5	Interquartile Range	11.5	30
Difference in anxiety scores between	Median	-13	0
time point 4 and time point 1	Interquartile Range	36.5	37.5
Difference in anxiety scores between	Median	-15**	-8**
time point 1 and time point 5	Interquartile Range	20	16.25
Difference in anxiety scores between	Median	5***	10***
time point 2 and time point 4	Interquartile Range	32.5	31.25
Difference in anxiety scores between	Median	0****	10****
time point 2 and time point 5	Interquartile Range	26.5	20

Change scores in anxiety levels\* significant at p = .004, \*\* significant at p = .009 \*\*\* significant at p = 0.049, \*\*\*\* significant at p = p = .019

In addition, the change in anxiety scores between the last time point at which the groups had been treated the same, i.e. after the induction of IHS time (point 2) to after watching the film (time point 4) there was a significant difference in the change in anxiety levels (hypnosis group Mdn = 5, story group Mdn = 10 U = 260 z = -1.97 p = .049), indicating that the story group anxiety levels went up more than the hypnosis group between these times.

In the hypnosis group anxiety levels reported at time point 2 were the same at the end of the experiment whilst the story group anxiety levels increased (Mdn change in anxiety between time point 2 and time point 5, hypnosis group = 0 story group =10 U = 238 z = -2.35 p = .019).

#### **Analysis of Groups Separately**

When the groups were considered separately, there was no significant difference in reported anxiety between the start of the experiment and the film in the story group (Mdn time point 1 = 5 Mdn time point 4 = 1.5) but in the hypnosis group there was a significant difference in reported anxiety levels, participants reported less anxiety after the film than when they arrived Mdn time point 1 = 5 Mdn time point 4 = -5, (T = 361 z = -3.11 p =.002 Wilcoxon Signed Rank Test). Using this to calculate an effect size for the film in the same way as experiment 1 reveals a tiny effect size for the film in the story group r = 0.07 but a medium negative effect size in the hypnosis group r = -0.41. When anxiety levels time point 4 and time point 5 were used to calculate an effect size, the values were very similar small effect sizes (story group r = 0.24, hypnosis group r = 0.21).

However, these change scores may not be the best analysis in this study as 'normal levels' have been defined as 0. When normal levels of 0 for each participant were compared to anxiety levels produced at time point 4 there was no significant difference in the story group (Mdn 1.5 T = 146.5 z = .259 ns.), whereas in the hypnosis group there was a significant difference (Mdn -5 T = 107.5 z = -1.962 p = .05). Using these results to calculate the effect size for the film in each group gives a medium effect size in the story group (r = 0.36) and an extremely small negative effect size in the hypnosis group (r = -0.03).

## **Relaxation levels**

These were measured on a reverse scale, lower scores represent more relaxation. The majority of this data was not normally distributed, as shown by positive results of the Kolmogorov –Smirnov and Shapiro-Wilk tests. Results for the Kolmogorov-Smirnov tests are given below in table 52.

	Story or Hypnosis	Kolmogorov-Smirnov test			
		Statistic (D)	df	significance	
Time point 1	Story	.296	26	.000	
_	Hypnosis	.265	29	.000	
Time point 2	Story	.227	26	.001	
-	Hypnosis	.155	29	.074	
Time point 3	Story	.264	26	.000	
_	Hypnosis	2	29	.005	
Time point 4	Story	.154	26	.115	
_	Hypnosis	.080	29	.2	
Time point 5	Story	.246	26	.000	
	Hypnosis	.174	29	.913	

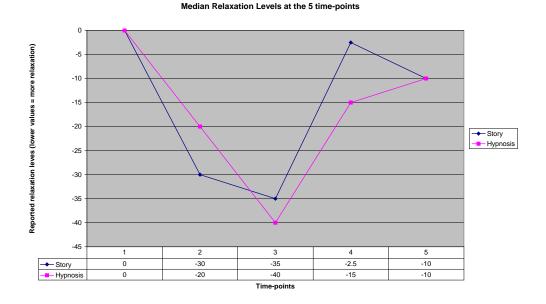
#### Table 52 normality test results for relaxation levels

Transformations of the data did not correct this. Non-parametric methods were therefore used. Descriptive statistics are shown below in table 53.

Hypnosis or story		Relaxation score surgery (time point 1)	Relaxation score nitrous oxide (time point 2)	Relaxation score intervention (time point 3)	Relaxation score film (time point 4)	Relaxation score end (time point 5)
Story n=26	Median	0	-30	-35	-2.5	-10
m-20	Interquartile range	5	26.25	35	46.25	10
Hypnosis n=29	Median	0	-20	-40	-15	-10
	Interquartile range	5	20	11	25	17.5

## Table 53 Descriptive statistics of relaxation levels throughout the experiment

Figure 13 Median relaxation levels at five time-points of the experiment (lower figures represent more relaxation)



#### **Change scores**

Change scores were calculated as for anxiety levels and there were no significant differences between the groups on the changes in relaxation scores between time points 1 and 2, time points 3 and 4 or time points 4 and 5. There is a significant difference in change in relaxation scores from after the IHS (time point 2) and after the intervention (time point 3), the hypnosis group showing a larger increase in relaxation than the story group (Mdn change hypnosis group = -15 Mdn change story group -9.5 U = 573 z = 3.33 p = .001). There is a significant difference between the groups in the change between time point 2 and time point 5, with the story group (Mdn change 20) becoming less relaxed than the hypnosis group (Mdn change 5) between those two time points (U = 527 z = 2.552 p = .011).

**Table 54 change scores in relaxation levels** 

	Statistic	Hypnosis	Story
Difference in relaxation scores between	Median	-20	-30
time point 1 and time point 2	Interquartile Range	17.5	26.24
Difference in relaxation scores between	Median	-15*	-9.5*
time point 2 and time point 3	Interquartile Range	12	15
Difference in relaxation scores between	Median	20	11.5
time point 3 and time point 4	Interquartile Range	31	37.5
Difference in relaxation scores between	Median	0	0
time point 4 and time point 5	Interquartile Range	65	36.25
Difference in relaxation scores between	Median	-15	-2.5
time point 4 and time point 1	Interquartile Range	31	42
Difference in relaxation scores between	Median	-15	-10
time point 1 and time point 5	Interquartile Range	15	20
Difference in relaxation scores between	Median	10	10
time point 2 and time point 4	Interquartile Range	28.5	32.5
Difference in relaxation scores between	Median	5**	20**
time point 2 and time point 5	Interquartile Range	25	26.25

**Change scores for relaxation levels** 

\* significant at p = .001, significant at p = .011

## **Analysis of Groups Separately**

With the groups considered separately using the Related Samples Wilcoxon Signed Rank Test, there was a significant increase in relaxation in the hypnosis group (time point 1 Mdn = 0 time point 4 Mdn = -15 (T = 346 z = 3.779 p =.000) Whereas there was no significant difference in the story group (time point 1 Mdn = 0 time point 4 Mdn = 2.5 (T = 180 z = 1.76 ns) giving effect sizes for the film as story group -0.24 (a small negative effect size) and hypnosis group, a medium to large negative effect size r = -0.49.

As for the anxiety scores, changes from 'normal levels' for the scores for relaxation at time point 4 were compared by group. In the story group there was no significant difference between normal levels of relaxation (0) and relaxation levels reported after the film (Mdn -2.5 T = 173.5 z = 1.531 ns) whereas the

hypnosis group showed significantly more relaxation than normal at time point 4 (Mdn -15 T = 330 z = -3.394 p = .001). Calculating effect sizes gives a small effect size for the film in the story group (r = 0.2) and a medium to large negative effect size in the hypnosis group (r = -0.44) (Field, 2005) (p 541).

#### **Correlation between anxiety levels and relaxation levels**

For the whole sample anxiety scores and relaxation scores were significantly correlated at all stages of the experiment, the less anxious a person reported being, the more relaxed they reported being: time point 1 r =.435 p = .001 (2-tailed); time point 2 r = .543 p =.000 (2-tailed); time point 3 r = .71 p = .000 (2 tailed); time point 4 r = .767 p = .000 (2-tailed); time point 5 r = .725 p = .000 (2-tailed) Highly significant correlations were also obtained when the groups were analysed separately except for after the IHS in the story group (r = .327 ns) and at the start of the experiment in the hypnosis group (r = .157 ns). MDAS and STAI(T) scores did not correlate with changes in anxiety produced by the film in either group.

## Discussion

#### **Anxiety levels**

The second experiment had some methodological improvements over the first. The scales gave a starting point for participants to anchor their normal feelings, thus making it easier for them to report changes. Allowing negative as well as positive changes allowed a greater flexibility in their reporting. Nevertheless, no between group differences were found on any of the measures. Although there were no group differences in anxiety levels whilst watching the film, the median anxiety levels in the hypnosis group did not reach baseline with 65% of participants reporting their anxiety as zero (how they normally feel) or less whilst watching the film, for the story group, the percentage was 50%.

The calculation of change scores enabled further comparisons. There were no differences between changes in anxiety levels between arrival and after IHS administration, IHS and before the film, before the film and after the film or after the film and the end of the experiment but the hypnosis group reduced their anxiety levels more than the story group from the start to the end of the experiment and from the start to after watching the film. Calculating the effect size for the film in the same way as experiment 1 (i.e. from the anxiety levels participants reported when they arrived (time 1) to after watching the film (time 4) reveals that this time the film had a moderate negative effect size in the hypnosis group and a very small positive effect size in the story group. There was no significant difference between the change in anxiety levels after the film and anxiety levels at the end of the experiment for either group, as the anxiety levels reported after the film were close to normal levels anyway. When anxiety levels at the start of the experiment and after the film were compared separately, there was a significant difference in the hypnosis group, but not the story group. The median anxiety levels in both groups fell but the median levels in the hypnosis group fell from 5 to -5 between their arrival and watching the film. This suggests that the hypnosis group were more anxious about the

experiment (anticipatory anxiety) than they were during the film. In addition, the anxiety levels during watching the film were not significantly different when compared to following IHS administration in the hypnosis group (although the median anxiety score did rise from median -15 to a median of -5); whilst in the story group they were significantly different, rising from a median of -20 to a median of 1.5.

Comparisons were made between 'normal levels' of anxiety as defined by the scales used as zero. This revealed that in the story group, there was still a medium effect size for the film, whilst in the hypnosis group the effect size was very small suggesting little or no effect of the film on normal anxiety levels in this group.

Overall the results show that both interventions produced reductions in anxiety levels more than the initial IHS, but this could be due to the extra time participants spent under sedation. This is unlikely as the sedative effects of IHS do not increase over time as this would have the potential to produce oversedation in patients, which typically does not happen when the technique is used clinically. Hypnosis produced a larger median drop in anxiety scores than the story.

Overall, hypnosis does seem to have effects on anxiety levels which is different to the story, but not sufficient to firmly reject the null hypothesis. This is partly due to statistical limitations which will be discussed later in this chapter.

#### **Relaxation levels**

The results for relaxation are similar to those for anxiety with no differences revealed between the groups at any of the time-points of the experiment. Change scores indicate that hypnosis produced a larger median increase in relaxation following IHS than the story did, but both groups showed reduced relaxation when watching the film. In addition, both groups showed more relaxation whilst watching the film than when they arrived. Most participants in the both groups were more relaxed at the end of the experiment than normal levels.

Since the hypnosis script contained specific relaxation instructions, the lack of clear differences between the groups on this measure is unexpected and seems to indicate that IHS alone has very effective relaxation properties, although, since the hypnosis group appeared to be less relaxed after IHS the increase in relaxation following the hypnosis procedure was significantly greater than in the story group.

After the film, relaxation scores in the story group rose to near normal levels (median = -2.5) whereas the hypnosis group maintained some of the increase in relaxation they had achieved (median = -15). Change scores indicate that there is a significant change (increase in relaxation from the start of the experiment to after watching the film) in the hypnosis group but not in the story group. However, despite apparently large median difference between the groups after the film, this was not statistically significant as the variability within the

samples was high, particularly in the story group (-40 to 25, interquartile range 46.25).

Effect sizes were calculated for the film both from the start of the experiment and compared to 'normal levels' (zero). In contrast to anxiety levels, both interventions were associated with negative effect sizes for the film which were medium to large in the hypnosis group and small in the story group. Both groups were MORE relaxed than normal when watching the film, the hypnosis group median relaxation level was -15 whilst the story group was almost at normal levels of -2.5. This suggests that hypnosis more effectively prevented relaxation levels from increasing to normal levels whilst watching the film than did the story.

#### **Correlations between anxiety and relaxation**

Correlations between the two measures were high confirming that the less anxious a person was feeling, the more relaxed they reported being. Causation cannot be assumed, as the link could be reversed i.e. that the more relaxed a person is, the less anxiety they felt. This concept is clinically useful and forms the basis of some forms of behavioural treatment for anxiety for example systematic desensitisation (Wolpe, 1958) where relaxation is assumed to be incompatible with anxiety.

# General discussion of Experiments 1 and 2

## Critique of methodology

Although experiment 2 was an improvement on experiment 1, there were still some problems with the methodology used.

#### Blinding

The Consort Statement has recently been improved and extended to make it more applicable to non-pharmacological trials, including trials of psychological or behavioural interventions. They pay special attention to the issue of blinding in such trials. They accept that blinding is more difficult to achieve in these types of trials and say that studies should report how successful the blinding methods were (Boutron et al., 2008a, Boutron et al., 2008b). In experiment 1 blinding of the experimenter was attempted, but blinding was broken in many cases as there were clear differences in the appearance of the participants in the hypnosis group. In experiment 2 therefore, blinding was not attempted and instead, interaction between the experimenter and the participants was minimised by using tape recordings more effectively including collection of self-report measures. However, the experimenter had some interaction with participants at the start and end of the experiment and therefore could have influenced responses at time-points 1, 2 and 5.

Partial blinding of participants was achieved by withholding information about what was being tested in the experiment. Those in the story group were not told that the study involved hypnosis to prevent the hold-back effect that could

otherwise have influenced their responses (Rainville, 2008, Braffman and Kirsch, 1999).

#### **Control procedure**

Although the control procedure (the story (Peake, 1992)) was carefully chosen not to contain emotional content, it is descriptive and absorbing. Absorption has been proposed to be related to suggestibility both non-hypnotic and hypnotic (Kirsch and Braffman, 2001, Braffman and Kirsch, 1999). In addition, absorption has been proposed to produce "a comfortable detachment from negative emotional occurrences" (Bowins, 2012) (p.311) and hence be useful in reducing anxiety. In addition, IHS has been shown to improve imaginative involvement (Whalley and Brooks, 2009). This could have been a confounding factor in this research. A better control procedure may have been to read a text book which may not have provided a focus for imaginative involvement and be more difficult for participants to become absorbed in.

The increases in relaxation and decreases in anxiety following the interventions could also be due to simple time effects – breathing the gas mixture for longer may have increased its effects. In order to rule this out, a second control group could have been used in which no verbalisations were provided at all. This was ruled out as potentially unacceptable to participants. An alternative may have been to use minimal verbalisations, simply encouraging participants to continue to breathe normally and ensuring that verbal contact was maintained.

## Critique of Analysis

Analysis of the results of both experiments was complicated due to unequal group sizes and significantly non-normal distributions. The preferred method of analysing trials such as this one, with baseline measures compared to the same measure at a follow-up time point is ANCOVA (analysis of covariance) (Vickers and Altman, 2001). This is because change scores do not actually control for baseline scores whereas ANCOVA is designed to account for some of the potentially unexplained variance and to remove confounding variables (Field, 2005).

However, because the data from these experiments are not normally distributed they do not conform to the assumptions for parametric tests. This may have been associated with a loss of power to detect a real difference. In experiment 1 the only option was to look at change scores to attempt to find real differences between the groups in the absence of absolute differences at each time point. In experiment 2, normal levels of anxiety and relaxation were defined at the start of the experiment as zero on the rating scale, thus there was a second option, which was to use the defined value of normal anxiety and normal relaxation in order to identify differences between the groups. This method was used in order to calculate effect sizes for the film in the two groups (Field, 2005).

However, multiple different comparisons have been carried out, and it is therefore more likely that statistically significant results will be found. This

increases the chance of type 1 error, in this case showing an effect for hypnosis where none exists.

### **Conclusions and Reflection**

Whilst these experiments have shown some statistically significant differences between anxiety produced by an anxiety stimulus in groups of normal volunteers randomised to two groups (IHS plus hypnosis and IHS plus reading a story), there is some doubt about the clinical significance of these results. Methodological issues as discussed above may account for this, or it may be that the effect of hypnosis is a weak effect given the effectiveness of IHS combined with a neutral reading of a story.

This type of controlled research using normal volunteers was chosen despite the loss of ecological validity associated with such designs due to the lack of previous studies in this area. However, on reflection, it may have been more valuable to carry out a randomised controlled clinical trial using anxious patients receiving dental treatment in order to more clearly answer the research question. Two groups of patients matched on MDAS scores and dental treatment need should be randomised to either IHS with a normal protocol (non-hypnotic reassurance) or IHS with a scripted hypnosis intervention. Both interventions would be difficult to standardise, but this type of trial is necessary in order to be a true test of the addition of hypnosis to IHS.

# **CHAPTER 5**

# **Discussion and Conclusions**

## Discussion of the results of the systematic review

Hypnosis has been used in dentistry for centuries. However, the systematic review provided no strong evidence for the effectiveness of hypnotic intervention for the alleviation of dental anxiety, particularly when patients who are highly anxious or phobic of dentistry are involved and where hypnosis is compared to other non-pharmacological treatments. This lack of strong evidence is partly due to the poor quality of studies that have been conducted so far.

Despite this, nine dentists in a recent survey of 460 general dental practitioners (GDPs) in the Midlands reported using hypnosis for anxious patients 'a lot' and a further 37 using it 'a little'. In addition, approximately 30% of the respondents expressed a definite desire for further training in hypnosis (Hill et al., 2008). It would seem therefore, that further clinical study is warranted in order to improve the quality of the evidence (or to show that these techniques do not have a place).

Some methodological issues found in the reviewed studies could easily be addressed. These include randomisation and allocation concealment procedures, which were most often unclear or unsatisfactory.

Other issues related to the plethora of outcome measures used. A discussion is needed to determine a more standardised set of outcome measures as the use of so many could reflect dissatisfaction with the self-report measures currently available. This issue is not just a problem in hypnosis studies, but also in studies of other psychological or behavioural interventions (Uman et al., 2006). There are few studies that used physiological measures alongside self-report and behavioural measures and sometimes where all three have been used they do not all predict treatment outcome (Mc Ammond et al., 1971). Issues relating to blinding of participants, study and treating personnel and outcome assessors were also highlighted in the review. It is difficult to blind patients to the fact that they had been hypnotised, but some studies have taken a creative approach to this by the use of sham hypnosis procedures (relaxation labelled as hypnosis) (Abrahamsen et al., 2009). In one non-dental study, the hypnotic intervention was not labelled hypnosis (Faymonville et al., 1997). It is not clear what effect these methods have on the responses of the participants, as the label 'hypnosis' has been shown to have beneficial effects (increased suggestibility and increased pain control respectively) compared to labelling the same procedure as hypnosis relaxation (Gandhi and Oakley, 2005, Hylands-White and Derbyshire, 2007). In order to take advantage of this, the studies reported in chapter 4, a different approach was taken, with the control group being blinded to the purpose of the study by not being informed that it was a study of hypnosis. It is also unclear whether any of these approaches provide adequate blinding.

Blinding of outcome assessors, however, should be possible and considered essential to reduce the risk of bias.

Large scale clinical studies would be necessary in order to investigate whether there are benefits to hypnosis. A model for this, in the case of oral surgery procedures in a hospital setting, could be the large scale clinical trial of

hypnosis and structured attention in interventional radiology (Lang et al., 2000). This trial included 241 patients and showed good methodology including a full description of randomisation process and blinding of operating personnel combined with objective outcome measures; for example amount of sedative and analgesic drug requested by patients during the procedure and the number of adverse events. These measures were complemented by the use of verbal self-report scales for pain and anxiety which were taken throughout the procedure, rather than simply before and after. This trial showed that hypnosis produced reports of less pain and anxiety over time despite the use of less medication. The study also showed an advantage for structured attention over standard treatment. Further analysis showed a cost benefit to the use of hypnosis with savings of, on average \$338 per patient compared to standard treatment (Lang and Rosen, 2002).

Studies involving highly anxious or phobic individuals were characterised by high levels of drop-outs. This should not be surprising as avoidance is one of the diagnostic criteria for the diagnosis of phobia. Most of these trials were set in specialist treatment centres (mainly in Scandinavia). Such centres do not exist in the UK and it has been suggested that such patients are commonly referred for treatment under IV sedation or GA with little attention paid to rehabilitation or treatment of their fear. This could be due to the perceived lack of training and lack of confidence in using psychological techniques (Hill et al., 2008). On the other hand, some dental patients are not offered conscious sedation when they need it and that services may be more demand-led than

needs led (Coulthard et al., 2011). Avoidance of oral care is a significant public health issue with a recent large telephone survey found that 17% did not attend the dentist regularly and that anxiety is the reason in many cases where patients have natural teeth (Goodwin and Pretty, 2011).

A large scale multi-centre trial investigating methods of enabling these patients to become regular attenders is necessary, as current evidence is not considered to be adequate due to flaws in research methods (Gordon et al., 2013). It is important that different psychological methods are compared to each other, rather than to no intervention. If such a trial was large enough sub group analysis could help to answer the question posed some years ago – what works for whom? (de Jongh et al., 2005).

# **Discussion of the experimental work**

Expert opinion has advised that 'a steady flow of reassuring and semi-hypnotic suggestion' is needed when using IHS (Roberts, 1990) p.140. To date, this has not been tested in randomised controlled trials. The experiments reported in chapter 4 were a first attempt to provide evidence that the addition of hypnotic techniques would reduce anxiety more than IHS alone in a parallel group randomised controlled trial.

The use of experimentally induced, temporary anxiety in volunteers rather than groups of anxious patients undergoing dental treatment aimed to provide proof of concept in advance of clinical trials.

The results of the studies were inconclusive in demonstrating a clear advantage for hypnosis over an audio recording of a story. Methodological issues have been discussed earlier in the relevant chapter and may have contributed to the lack of clear findings.

However, there were some indications that hypnosis may provide some benefit in keeping anxiety levels below normal as defined in experiment two. It was also planned to investigate the relationship between IHS and hypnosis by going on to test whether the addition of IHS to hypnosis improved the effectiveness of hypnosis alone. A protocol for this study was developed, but the study was not carried out due to the difficulties in obtaining ethical approval for a study of a clinical trial of a medicinal product. The protocol for this proposed study - Hypnosis alone versus hypnosis plus nitrous oxide inhalation sedation to reduce experimental dental anxiety was developed and can be found in appendix 5. A cross-over trial (Whalley and Brookes, 2009) has demonstrated that IHS has effects on suggestibility and imaginative ability so the planned study could have been useful in testing these types of effects in a dental setting.

# Conclusions

Overall, this thesis indicates that evidence for hypnosis in dental anxiety has a low level of evidence for its efficacy. Nevertheless, interest in its use amongst dentists and members of the public remains high. Further research is needed; both experimental investigations and clinical trials are recommended.

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# Appendices

## **Appendix 1 – Licence agreement**

Title: Hypnosis for alleviation of anxiety in adults undergoing dental treatment Author: Catherine Potter, Paul Coulthard, Richard Brown, Tanya Walsh Publication: Cochrane Database of Systematic Reviews Publisher: John Wiley and Sons Date: Aug 14, 2013 Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. This is a License Agreement between Catherine Potter ("You") and John Wiley and Sons ("John Wiley and Sons"). The license consists of your order details, the terms and conditions provided by John Wiley and Sons, and the payment terms and conditions. License Number 3264721378272 License date Nov 09, 2013 Licensed content publisher John Wiley and Sons Licensed content publication Cochrane Database of Systematic Reviews Licensed content title Hypnosis for alleviation of anxiety in adults undergoing dental treatment Licensed copyright line Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. Licensed content author Catherine Potter, Paul Coulthard, Richard Brown, Tanya Walsh Licensed content date Aug 14, 2013 Type of use Dissertation/Thesis Requestor type Author of this Wiley article Format Print and electronic

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## Appendix 2 – Documentation for studies 1&2 Chapter 3

### Text of email advert for recruitment (studies 1&2)

Re: Earn £5 for helping with a study about dental anxiety

I am a PhD student at the University of Manchester schools of Dentistry and Psychology.

We are looking for volunteers to take part in a study about dental anxiety. You will be asked to sit in a dental chair and watch a film showing unpleasant dentistry. We will monitor your anxiety levels and ask you to fill in some questionnaires. We will pay you £5 for your time.

The Questionnaires will take about 5minutes to fill in online and the study will take no more than 45 minutes of your time when you attend.

If you would like to help, please follow the link below and read the full information sheet before continuing.

Thanks for your help

Cath

Cath Potter

Catherine.potter@manchester.ac.uk

(A link to the secure website will be inserted here)

number:



PARTICIPANT INFORMATION SHEET

Title of project:

A pilot study to investigate the effect of watching a film involving dentistry on anxiety levels

## Introduction

In order to study emotions such as anxiety, psychologists have tried to develop methods of producing these emotions under controlled conditions. One common method is to present participants with emotional excerpts from feature films. This pilot study is designed to test whether watching a film depicting unpleasant dental experiences will increase anxiety levels. We hope that this research will allow us to develop a method for inducing temporary dental anxiety so that we can improve our treatments for people suffering from dental anxiety and phobias.

The study will take place in the Dental School.

## What will I be asked to do if I take part?

Before and during the experiment you will be asked to fill in some questionnaires about:

- 1. Your attitude to dentistry the modified dental anxiety scale this asks questions such as: If you went to your Dentist for treatment tomorrow, how would you feel? And, If you were about to have a tooth drilled, how would you feel?
- 2. Your levels of anxiety in general the Spielberger State/Trait Anxiety Inventory. This asks you to rate statements such as: 'I

feel calm' and 'I am jittery' 'I am content' and 'Some unimportant thought runs through my mind and bothers me'.

3. You will also be asked to rate your anxiety on a scale of 0-100 Your heart rate will be measured non-invasively.

Then you will be asked to sit in a dental chair in a dental surgery set up

with a full range of dental equipment. Your anxiety levels and heart rate

will be monitored throughout the time you are there. You will then watch

a film clip which depicts frightening uses of dentistry.

No dental treatment is involved in this study.

The whole experiment should take no more than 45minutes.

Following the experiment, here will be an opportunity to discuss your

experience with the researcher if you wish.

### Will my data be anonymous?

Yes. Your responses will be recorded on a sheet which has a number on it but not your name. This will not be linked to your name in any way and the data sheets and consent forms will be kept separate. The data will later be entered onto a computer, but without any names being used. Consent forms will be stored separately in a locked filing cabinet.

### Do I have to take part?

You do not have to take part in the study. If you decide to take part and

then later change your mind, either before you start the study or during

it, you can withdraw without giving any reasons, and if you wish, any

data will be destroyed. We will not be able to destroy your data after

completing the study because we will not keep a record of your personal details which is linked to your responses. However, we would like to reassure you that this means your identity is completely protected.

## Where can I obtain further information if I need it?

You may contact me by email at Catherine.potter@manchester.ac.uk or

by telephone at Ordsall Clinic on 0161 212 4755

You may also contact my supervisors:

Professor Paul Coulthard: paul.coulthard@manchester.ac.uk

Dr. Richard J. Brown:

richard.james.brown@manchester.ac.uk

## What happens next?

If you decide to volunteer, please answer the following questions:

1. Have you read the Participant Information Sheet?	YES/NO
2. Have you received enough information about the study?	YES/NO
3. Do you understand that you do not need to take part in the	YES/NO
study and if	
you do enter you are free to withdraw:-	
* at any time	
* without having to give a reason for withdrawing	
* and without detriment to you?	

## 4. Do you agree to take part in this study?

If you have agreed to take part in the study, you will be sent an appointment to attend the Dental Hospital. If the appointment is not convenient, please email me and we will rearrange it for a more convenient time

Thank you for your attention.

## Appendix 3 – Documentation for study 1 chapter 4

Wording of website recruitment Email pack with questionnaires

Participant information sheets

#### Text of email advert for study recruitment

RE: Paid volunteers sought for a study of nitrous oxide and dental anxiety Would you like to help to combat dental anxiety and experience nitrous oxide sedation?

I am a PhD student at the University of Manchester schools of Dentistry and Psychology.

We are looking for volunteers to take part in a study of how nitrous oxide affects dental anxiety.

If you are fit and well and not normally phobic about dentistry we would like you to volunteer. You would receive nitrous oxide which is used by dentists to combat anxiety and is generally regarded as a pleasant experience.

You will be asked to fill in some questionnaires, come to the dental school and watch a film of unpleasant dentistry whilst breathing nitrous oxide. We will monitor your anxiety levels during the study.

The study will take no more than one and a half hours of your time when you attend, including recovery time. Afterwards, you will be able to return to your normal activities.

If you are interested please contact me



Thank you,

Cath Potter

number:

## PARTICIPANT INFORMATION SHEET Title of project:

A study to investigate the effect on experimental dental anxiety of sedation with a mixture of nitrous oxide and oxygen combined with listening to tape recordings.

### Introduction

Dentists use mixtures of nitrous oxide gas and oxygen to reduce dental anxiety in their patients. The gas/oxygen mixture is breathed in through a nose piece; it may have a slightly sweet but not unpleasant odour. The nitrous oxide is introduced slowly until you feel relaxed and comfortable.

This is an extremely safe process and is generally experienced as very pleasant and relaxing. To improve the effectiveness of the technique we wish to test whether the addition of listening to tape recordings will improve the anxiety reduction.

Although you may not ordinarily be anxious about dentistry we will be produce temporary anxiety in a controlled way by asking you to watch a film depicting unpleasant dental experiences. We hope that this research will allow us to improve our treatments for people suffering from dental phobias. The study will take place in the Dental School – Higher Cambridge

Street (behind Manchester Museum).

## What will I be asked to do if I take part?

Before and during the experiment you will be asked to fill in some

questionnaires:

- 1. A standard medical history form
- Your attitude to dentistry the modified dental anxiety scale this asks questions such as: If you went to your Dentist for treatment tomorrow, how would you feel? And, If you were about to have a tooth drilled, how would you feel?
- 3. Your levels of anxiety in general the Spielberger State/Trait Anxiety Inventory. This asks you to rate statements such as: 'I feel calm' and 'I am jittery' 'I am content' and 'Some unimportant thought runs through my mind and bothers me'.
- 4. You will also be asked to rate your anxiety on a scale of 0-100 Your heart rate will be measured non-invasively.

Then you will be asked to sit in a dental chair in a dental surgery set up

with a full range of dental equipment. Your anxiety levels and heart rate

will be monitored throughout the time you are there.

You will breathe the nitrous oxide and oxygen until you feel relaxed and

comfortable and listen to a spoken word recording.

You will then watch a film clip which depicts frightening uses of dentistry.

At the end of the experiment the sedation will be reversed by breathing pure oxygen for 2-5 minutes then you will rest in the waiting room for about 20 minutes to make sure you are completely recovered.

There are very few side effects of nitrous oxide, but rarely some people may feel some slight nausea which is easily reversed by turning off the gas and breathing oxygen. You should eat and drink normally before you attend but abstain from alcohol. There are normally no after effects and you will be able to return to your normal day to day activities.

No dental treatment is involved in this study.

The whole experiment should take about 11/2 hours including recovery time.

Following the experiment, here will be an opportunity to discuss your experience with the researcher if you wish.

#### Will my data be anonymous?

Yes. Your responses will be recorded on a sheet which has a number on it but not your name. This will not be linked to your name in any way and the data sheets and consent forms will be kept separate. The data will later be entered onto a computer, but without any names being used. Consent forms will be stored separately in a locked filing cabinet.

#### Do I have to take part?

You do not have to take part in the study. If you decide to take part and then later change your mind, either before you start the study or during it, you can withdraw without giving any reasons, and if you wish, any data will be destroyed. We will not be able to destroy your data after completing the study because we will not keep a record of your personal details which is linked to your responses. However, we would like to reassure you that this means your identity is completely protected.

#### Where can I obtain further information if I need it?

You may contact me by email at <u>Catherine.potter@manchester.ac.uk</u> or by telephone at Ordsall Clinic: 0161 212 4755

You may also contact my supervisors:

Professor. Paul Coulthard: paul.coulthard@manchester.ac.uk

Dr. Richard J. Brown:

richard.james.brown@manchester.ac.uk

#### What happens next?

If you decide to volunteer, please answer the following questions:

1. Have you read the Participant Information Sheet?	YES/NO
2. Have you received enough information about the study?	YES/NO

3. Do you understand that you do not need to take part in the	YES/NO
study and if	
you do enter you are free to withdraw:-	
* at any time	
* without having to give a reason for withdrawing	
* and without detriment to you?	
4. Do you agree to take part in this study?	YES/NO

Have you taken part in any other psychological research?

If yes, please give

details:

.....

If you have agreed to take part in the study, you will be sent an appointment to attend the Dental Hospital. If the appointment is not convenient, please email me and we will rearrange it for a more convenient time

Thank you for your attention.

Please proceed to the questionnaires.



## CONFIDENTIAL MEDICAL HISTORY FORM

To make your participation on this study safe for you we need to know of any problems which may affect your health. If you have any problems answering this questionnaire please contact me by email on <u>Catherine.potter@manchester.ac.uk</u>.

HOW LONG SINCE YOUR LAST DENTAL VISIT?.....

Date of Birth	Male or Female (delete as
necessary)	

Please delete as necessary. If you answer yes to any question, please give further details at the end of the form.

### ARE YOU:

- 1. Attending or receiving treatment from a doctor, clinic or specialist? Y N
- Taking any medicines from your doctor (Tablets, creams, self prescribed medication or drugs, inhalers, other? Y N
- 3. Taking or have you taken steroids in the last two years? Y N
- 4. Allergic to any medicines, foods or materials? YN
- 5. Carrying a medical warning card? Y N

HAVE YOU:

- 6. Had rheumatic fever or chorea (St Vitus Dance)? Y N
- 7. Had jaundice, hepatitis, liver disease or kidney disease? Y N
- 8. Have you been exposed to a high risk of, or do you suffer from tuberculosis or AIDS? Y N

- 9. Ever been told you have a heart murmur or heart problem, angina, blood pressure, or had a heart attack? YN
- 10. Had a bad reaction to a general or local anaesthetic or sedation procedure?
- 11. Had a joint replacement? Y N
- 12. Been Hospitalised? If so, what for and when? Y N
- 13. Do you suffer from any physical or mental illness or serious disability? Y N
- 14. Had brain surgery or received growth hormone treatment? Y N
- 15. Have you ever been treated with bleomycin? Y N
- 16. Have you had eye surgery within the last 6 months? Y N

#### DO YOU:

- 17. Have a close relative with Creutzfeldt-Jakob disease? Y N
- 19. Suffer from bronchitis, asthma or other chest condition? Y N
- 20. Have fainting attacks, giddiness, blackouts or epilepsy? Y N
- 21. Have diabetes? Y N

- 22. Bruise easily, or following a tooth extraction, have you or your family bled so as to cause you to be worried? Y N
- 23. Suffer from multiple sclerosis or myasthenia gravis? Y N
- 24. Are there any other aspects of your health that you think we should know? Y N

#### WOMEN ONLY

25. Are you, or do you think you may be pregnant? Y N

26. Are you breast feeding? Y N

If you have answered yes to any of the above questions, please give further details:

no:

MANCH

#### CAN YOU TELL US HOW ANXIOUS YOU GET, IF AT ALL, WITH YOUR DENTAL VISIT? PLEASE INDICATE BY INSERTING 'X' IN THE APPROPRIATE BOX

## 1. If you went to your Dentist for TREATMENT TOMORROW, how would you feel?

Not Anxious
Slightly Anxious
Fairly Anxious
Very Anxious
Extremely Anxious

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

Not Anxious	ſ
Slightly Anxious	Ī
Fairly Anxious	[
Very Anxious	[
Extremely Anxious	[

## 3. If you were about to have a TOOTH DRILLED, how would you feel?

Not Anxious	Γ
Slightly Anxious	
Fairly Anxious	
Very Anxious	Ľ
Extremely Anxious	

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

Not Anxious	
Slightly Anxious	C
Fairly Anxious	
Very Anxious	
Extremely Anxious	

## 5. If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above

### an upper back tooth, how would you feel?

Not Anxious [ Slightly Anxious [ Fairly Anxious [ Very Anxious [ Extremely Anxious [

#### SELF-EVALUATION QUESTIONNAIRE STAI Form Y-2

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then select the appropriate number to the right of the statement to indicate how you **generally** feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally

feel.	
1001.	

	Almost Never	Sometimes	Often	Almost Always
	1	2	3	4
1.I feel pleasant	0	0	0	0
2. I feel nervous and restless	0	0	0	0
3. I feel satisfied with myself	0	0	0	0
4. I wish I could be as happy as others seem to be	0	c	0	c
5. I feel like a failure	0	0	0	0
6. I feel rested	0	0	0	0
7. I am "calm, cool, and collected"	0	0	0	0
8. I feel that difficulties are piling up so that I cannot overcome them	0	0	0	0
9. I worry too much over something that really doesn't matter	0	0	0	0

10. I am happy	0	0	0	0
11. I have disturbing thoughts	0	0	0	0
12. I lack self-confidence	0	0	0	0
13. I feel secure	0	0	0	0
14. I make decisions easily	0	0	0	0
15. I feel inadequate	0	0	0	0
16. I am content	0	0	0	0
17. Some unimportant thought runs through my mind and bothers me	0	0	0	0
18. I take disappointments so keenly that I can't put them out of my mind	0	0	o	0
19. I am a steady person	0	0	0	0
20. I get in a state of tension or turmoil as I think over my recent concerns and interests	c	c	0	c

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no



#### **PARTICIPANT INFORMATION SHEET 2A**

Thank you for volunteering for this study and for your completed questionnaires.

This information sheet is to give you a little more information about what you can expect when you attend for the study.

As you probably know, nitrous oxide is used thousands of times a day all over the world to help make dental treatment more comfortable. We would like to give you more information about how nitrous oxide works because it may be that the more you know about any medicine or treatment you receive, then the better that treatment will work.

It is important that you know that nitrous oxide, in low doses, seems to be effective as a sedative and pain reliever in dentistry. The technique that we use is called inhalation sedation and it is a very safe use of nitrous oxide.

One way that nitrous oxide works is as a sedative or tranquiliser. It lowers the brain's level of consciousness about anxiety and pain, making people feel good. The first signs that nitrous oxide is changing how your brain is processing information comes from changes you can readily experience with lower doses of nitrous oxide – your toes, maybe your fingers may begin tingling and a kind of warm glow may come over you; a feeling of relaxation of muscle tension. This feeling of relaxation helps to reduce anxiety levels and generally feels very pleasant.

We are interested in how little or how much anxiety you feel at various times during the experiment and how this changes. We will play you a story tape during the session and you will also watch part of a film which shows scenes of unpleasant dentistry.

We would like to remind you that you do not have to take part in the study. If you decide to take part and then later change your mind, either before you start the study or during it, you can withdraw without giving any reasons, and if you wish, any data will be destroyed. We will not be able to destroy your data after completing the study because we will not keep a record of your personal details which is linked to your responses. However, we would like to reassure you that this means your identity is completely protected.

#### Where can I obtain further information if I need it?

You may contact me by email at <u>Catherine.potter@manchester.ac.uk</u> or by telephone at Ordsall Clinic on 0161 212 4755

You may also contact my supervisors:

Professor Paul Coulthard: paul.coulthard@manchester.ac.uk

Dr. Richard J. Brown: richard.james.brown@manchester.ac.uk

no:



#### **PARTICIPANT INFORMATION SHEET 2B**

Thank you for volunteering for this study and for your completed questionnaires.

This information sheet is to give you a little more information about what you can expect when you attend for the study. We will be investigating the effects of hypnosis on the actions of nitrous oxide.

As you probably know, nitrous oxide is used thousands of times a day all over the world to help make dental treatment more comfortable. We would like to give you more information about how nitrous oxide works because it may be that the more you know about any medicine or treatment you receive, then the better that treatment will work.

It is important that you know that nitrous oxide, in low doses, seems to be effective as a sedative and pain reliever in dentistry. The technique that we use is called inhalation sedation and it is a very safe use of nitrous oxide.

One way that nitrous oxide works is as a sedative or tranquiliser. It lowers the brain's level of consciousness about anxiety and pain, making people feel good. The first signs that nitrous oxide is changing how your brain is processing information comes from changes you can readily experience with lower doses of nitrous oxide – your toes, maybe your fingers may begin tingling and a kind of warm glow may come over you; a feeling of relaxation of muscle tension. This feeling of relaxation helps to reduce anxiety levels and generally feels very pleasant.

We are interested in how little or how much anxiety you feel at various times during the experiment and how this changes. We will play you an audio recording of a hypnotic induction procedure along with hypnotic suggestions for calmness and anxiety control during the session and you will also watch part of a film which shows scenes of unpleasant dentistry.

#### **Hypnosis**

Hypnosis is a procedure during which the hypnotist attempts to influence the participant's perceptions, feeling, thinking and behaviour by asking them to concentrate on ideas and images that may evoke the intended effects. These verbal communications are termed 'suggestions'. In this experiment the hypnosis will be delivered by means of an audio recording and will include:

- A hypnotic 'induction' which will give suggestions for relaxation and for becoming absorbed in your inner experiences such as feelings, thoughts and imagery.
- This will be followed by suggestions for calmness, relaxation and wellbeing to continue after the hypnosis.

Most people find hypnosis to be a pleasant experience.

#### Are there any side effects or risks of hypnosis?

Risks from hypnotic procedures are few and minor. In fact research has shown that the majority of participants report positive after-effects such as relaxation. A minority of people have reported minor after-effects such as headache, dizziness, nausea or stiff neck. However, these are no more frequent after hypnosis than after other experiments that do not involve hypnosis

We would like to remind you that you do not have to take part in the study. If you decide to take part and then later change your mind, either before you start the study or during it, you can withdraw without giving any reasons, and if you wish, any data will be destroyed. We will not be able to destroy your data after completing the study because we will not keep a record of your personal details which is linked to your responses. However, we would like to reassure you that this means your identity is completely protected.

#### Where can I obtain further information if I need it?

If you need general information about the project, or information about the actions or effects of nitrous oxide you may contact me by email at <u>Catherine.potter@manchester.ac.uk</u> or by telephone at Ordsall Clinic: 0161 212 4755

If you need to know more about hypnosis before taking part please contact Dr. Richard J. Brown on: <u>richard.james.brown@manchester.ac.uk</u>, or telephone:0161 276 5392

You may also contact my supervisors:

Professor. Paul Coulthard: paul.coulthard@manchester.ac.uk

Dr. Richard J. Brown: richard.james.brown@manchester.ac.uk

## **Appendix 4 Hypnosis scripts**

## **Experiment 1**

Just make yourself as comfortable as you can in the chair. Let yourself really settle down in the chair and feel the chair comfortable and really supporting your body. Close your eyes and just listen to the sound of my voice. And as you do just really concentrate on your breathing and notice that, as you breathe, as you breathe in you can feel the tension in your chest and as you breathe out notice how everything can feel more relaxed and more comfortable. And just let all the muscles in your head and your face feel really heavy, comfortable, totally relaxed.

And as you breathe just spread that feeling down through the muscles of your neck, and your shoulders, breathe away all the tension that you gather there in the course of the day. All the muscles of your shoulders relaxed comfortable heavy and floppy.

#### ABOUT 2 MINS

And then just allow that relaxation to spread down the muscles of your arms, the muscles of the top of your arms, your elbows, your forearms all the way down into your hands right down to the very tips of your fingers.

And the muscles of your chest and your back, as you breathe, just let them relax. So relaxed so comfortable and then just spread that all the way down through your tummy, your hips and into your legs, and your feet, all the way down to the very tips of your toes. And just notice how relaxed and how comfortable your whole body can feel. The muscles of your eyes and your eyelids, so heavy, so relaxed and so comfortable that even if you wanted to, it would be far too much trouble to open them.

And you know that in hypnosis, when you relax like this you can also relax your mind as well as your body. I'd like you to imagine that you are standing at the top of a flight of steps looking down. Looking down onto a beautiful place, a special place that can be anything you want it to be. ABOUT 5MINS Anywhere, anywhen. And the flight of steps is going to take you there whilst you go deeper and deeper and deeper and deeper and deeper into hypnosis. Let yourself see in the eye of your mind that flight of steps leading down, 20 steps. And in a moment you're going to walk down those steps, and with every step that you take you're going to become more relaxed more comfortable and sink deeper and deeper and deeper into hypnosis, so, - 1 more and more deeply relaxed and 2, deeper and deeper 3, 4, much more deeply relaxed than you were before, more and more comfortable. 5, 6, deeper and deeper, deeper and deeper more and more comfortable more and more relaxed. 7, 8, 9, and 10 half way to being really, really deeply, deeply, deeply relaxed and hypnotised. And you don't have to do anything you don't even have to listen to me, just let yourself sink deeper and deeper and deeper, deeper and deeper into hypnosis 11, 12 with every number really deeply relaxed now. 13, 14, 15, almost there now. ABOUT 10 MINS

So deeply relaxed now so comfortable that nothing needs to bother you nothing needs to disturb you, all the sounds you could hear before just fading away,

nothing but the sound of my voice. 16, 17, 18, 19, and 20. So relaxed, so comfortable. And now you're at the bottom of those steps just let yourself look all around in your special place anything you want can be there. Any people you want can be there, but you may want to be completely on your own. Look all around and see all the things that you can see, the shapes of things, the colours of things. Just allow yourself to completely enjoy seeing all the things you need around you. Let yourself hear the sounds in that special place, smell the air. If you want you can touch things, pick things up, all the things that are around you. And most of all just enjoy being there, enjoy that feeling of complete relaxation and comfort. So calm, so comfortable so completely relaxed.

And this special place can be somewhere you can come back to whenever you want to, And whenever you need to. Just to recharge your batteries and to allow yourself to become totally calm, controlled and completely relaxed. And whilst you're in that special place you can just really enjoy it. And while you're enjoying it, I'm gonna talk to you, but you don't need to listen, you don't need to do anything. Little bit like being a passenger in a car, where you can just enjoy being completely calm, completely relaxed, letting someone else do all the work. 15 MINS

Now sometimes we all have things that make us worried or anxious. And today might be one of those things, but by using the power of our minds and the power of hypnosis you can control that anxiety, and you can remain totally relaxed, totally comfortable and very calm, whatever you see, or hear, or

experience nothing needs to bother you, nothing needs to concern you. You can stay completely relaxed, completely calm, completely in control of how you feel and nothing that you see or hear or experience will bother you or disturb you in any way. Even when you are completely awake.

Because your mind is calm, your body is relaxed and you can stay relaxed and calm and controlled for as long as you want to and as long as you need to. And any time that you need to feel really calm, really comfortable and really relaxed all you will do is to just remember your special place and how calm and comfortable you're feeling right now. And any time that anyone or anything tries to bother you or disturb you, you'll just find that you think to yourself of your special place and the words Calm, Comfortable and Completely relaxed, and the disturbance and the anxiety and the worry will just disappear. So that you can stay just as calm, just as comfortable and just as relaxed as you are right now. And as you breathe and as you relax in the chair, that comfort and that calmness can be building and building and building so that in a moment you will feel even more calm, even more relaxed and even more comfortable than you are right now. And in the future, whether you're relaxed like this, or whether you're up and about and active those feelings of calmness comfort and relaxation can be with you whenever you need them. So that if anything is bothering you or disturbing you, you can just put that out of your mind so that you can return to being completely calm, comfortable, completely relaxed, just as calm and relaxed as you are right now. And in a moment, I'm going to ask you to open your eyes and I'm going to ask you to watch a film, which in the

past might have bothered you, but now, you can stay completely calm, completely comfortable and completely relaxed. Nothing needs to bother you or disturb you. Nothing needs to make you anxious, anything that bothers you can just drift away into the background and you can just stay just as calm, just as relaxed, just as comfortable as you are right now. And from this day on, and the rest of your life, you'll find that you can be much calmer in the face of anything that would have bothered you. You can be much more comfortable with things that may have bothered you. You can be much more confident in your ability to deal with things that may have bothered you. Even when you're up and about and active these feelings of calmness confidence, control and comfort can remain with you. More calm more confident more able to deal with anything that in the past may have bothered you or disturbed you. So in a moment I'm going to ask you to open your eyes and watch the video, and whilst you're watching it you'll remain completely aware of how calm you are, how comfortable you are and how relaxed you can be. And anything that may have bothered you or disturbed you in the past can just drift away into the background into a minor irritation that you can ignore and remain calm, comfortable and completely relaxed.

In a moment I'm gonna count from 5 to 1, and on 5 you'll remain just as relaxed as you are now. And then bit by bit with each number you can become more and more awake and alert. Feeling refreshed and comfortable, as if you've just had a really good night's sleep. And you can bring back with you all the calmness and the comfort that you've felt today, so that anything that you see,

or hear, or experience will have no power to disturb you, or bother you, or make you anxious in any way.

Ok, so...

5, starting to wake and come back to the here and now. 4 becoming more alert now, bringing back with you the knowledge and ability to remain completely calm, completely comfortable and completely relaxed, whatever you see, or hear, or experience. 3, remembering that whilst you watch the video, you will stay calm, relaxed and comfortable and that nothing needs to bother you or disturb you. 2, and 1 wide awake and refreshed, ready for the rest of the day. Alternative arousal

I'm going to start counting now. 5, 4, 3, remembering to bring back with you all that calmness, comfort and relaxation 2, starting to feel more alert and refreshed and ready to face the rest of the day and 1 all the way back now, awake and alert and ready to face the rest of the day.

### **Experiment 2**

Just make yourself as comfortable as you can in the chair. Let yourself really settle down in the chair and feel the chair comfortable and really supporting your body. Close your eyes and just listen to the sound of my voice. And as you do just really concentrate on your breathing and notice that, as you breathe, as you breathe in you can feel the tension in your chest and as you breathe out notice how everything can feel more relaxed and more comfortable. And just let all the muscles in your head and your face feel really heavy, comfortable, totally relaxed.

And as you breathe just spread that feeling down through the muscles of your neck, and your shoulders, breathe away all the tension that you gather there in the course of the day. All the muscles of your shoulders relaxed comfortable heavy and floppy.

#### 2.18 MINS

And then just allow that relaxation to spread down the muscles of your arms, the muscles of the top of your arms, your elbows, your forearms all the way down into your hands right down to the very tips of your fingers. And the muscles of your chest and your back, as you breathe, just let them relax. So relaxed so comfortable and then just spread that all the way down through your tummy, your hips and into your legs, and your feet, all the way down to the very tips of your toes. And just notice how relaxed and how comfortable your whole body can feel. The muscles of your eyes and your eyelids, so heavy, so relaxed and so comfortable that even if you wanted to, it would be far too much trouble to open them.

And you know that in hypnosis, when you relax like this you can also relax your mind as well as your body.

I'd like you to imagine that you are standing at the top of a flight of steps looking down. Looking down onto a beautiful place, a special place, that can be anything you want it to be. 4.45MINS

Anywhere or anywhen. And the flight of steps is going to take you there whilst you go deeper and deeper and deeper and deeper and deeper into hypnosis. Let yourself see in the eye of your mind that flight of steps leading down, 20 steps. And in a moment you're going to walk down those steps, and with every step that you take you're going to become more relaxed more comfortable and sink deeper and deeper and deeper into hypnosis, so, - 1 more and more deeply relaxed and 2, deeper and deeper 3, 4, much more deeply relaxed than you were before, more and more comfortable. 5, 6, deeper and deeper, deeper and deeper more and more comfortable. 5, 6, deeper and deeper, deeper and deeper more and more comfortable more and more relaxed. 7, 8, 9, and 10 half way to being really, really deeply, deeply, deeply relaxed and hypnotised. And you don't have to do anything you don't even have to listen to me, just let yourself sink deeper and deeper and deeper, deeper and deeper into hypnosis 11, 12 with every number really deeply relaxed now. 13, 14, 15, almost there now. 8.25 MINS

So deeply relaxed now so comfortable that nothing needs to bother you nothing needs to disturb you, all the sounds you could hear before just fading away, nothing but the sound of my voice. 16, 17, 18, 19, and 20. So relaxed, so comfortable. And now you're at the bottom of those steps just let yourself look all around in your special place anything you want can be there. Any people you want can be there, but you may want to be completely on your own. Look all around and see all the things that you can see, the shapes of things, the colours of things. Just allow yourself to completely enjoy seeing all the things you need around you. Let yourself hear the sounds in that special place, smell

the air. If you want you can touch things, pick things up, all the things that are around you. And most of all just enjoy being there, enjoy that feeling of complete relaxation and comfort. So calm, so comfortable so completely relaxed.

And this special place can be somewhere you can come back to whenever you want to, And whenever you need to. Just to recharge your batteries and to allow yourself to become totally calm, controlled and completely relaxed. And whilst you're in that special place you can just really enjoy it. And while you're enjoying it, I'm gonna talk to you, but you don't need to listen, you don't need to do anything. Little bit like being a passenger in a really safe car, where you can just enjoy being completely calm, completely relaxed, letting someone else do all the work. 13.09 MINS

Now sometimes we all have things that make us worried or anxious. And today might be one of those things, but by using the power of our minds and the power of hypnosis you can control that anxiety, and you can remain totally relaxed, totally comfortable and very calm, whatever you see, or hear, or experience nothing needs to bother you, nothing needs to concern you. You can stay completely relaxed, completely calm, completely in control of how you feel and nothing that you see or hear or experience will bother or disturb you in any way. Even when you are completely awake.

Because your mind is calm, your body is relaxed and you can stay relaxed and calm and controlled for as long as you want to and as long as you need to. And any time that you need to feel really calm, really comfortable and really relaxed

all you will do is to just remember your special place and how calm and comfortable you're feeling right now. And any time that anyone or anything tries to bother you or disturb you, you'll just find that you think to yourself of your special place and the words Calm, Comfortable and Completely relaxed, and the disturbance and the anxiety and the worry will just disappear. So that you can stay just as calm, just as comfortable and just as relaxed as you are right now. And as you breathe and as you relax in the chair, that comfort and that calmness can be building and building and building so that in a moment you will feel even more calm, even more relaxed and even more comfortable than you are right now. And in the future, whether you're relaxed like this, or whether you're up and about and active those feelings of calmness comfort and relaxation can be with you whenever you need them. So that if anything is bothering you or disturbing you, you can just put that out of your mind so that you can return to being completely calm, comfortable, completely relaxed, just as calm and relaxed as you are right now. And in a moment, I'm going to ask you to open your eyes and I'm going to ask you to watch a film, which in the past might have bothered you, but now, you can stay completely calm, completely comfortable and completely relaxed. Nothing needs to bother you or disturb you. Nothing needs to make you anxious, anything that bothers you can just drift away into the background and you can just stay just as calm, just as relaxed, just as comfortable as you are right now. And from this day on, and the rest of your life, you'll find that you can be much calmer in the face of anything that would have bothered you. You can be much more comfortable with things

that may have bothered you. You can be much more confident in your ability to deal with things that may have bothered you. Even when you're up and about and active these feelings of calmness confidence, control and comfort can remain with you. More calm more confident more able to deal with anything that in the past may have bothered you or disturbed you. So in a moment I'm going to ask you to open your eyes and watch the video, 22mins

OK ... so in a moment I'm going to ask you to open your eyes. You will find that you can do this without disturbing your hypnosis or your relaxation. When your eyes are open I will ask you to give me a score on the scales we used earlier for anxiety and relaxation. You will find it very easy to do this whilst staying just as deeply relaxed and hypnotised as you are right now. Ok I'll count to 3 and then your eyes will open and your body and your mind will stay just as relaxed and deeply hypnotised as you are right now. 1, 2, 3 open your eyes now and stay deeply relaxed and deeply hypnotised. Now please give me a number on the scale for anxiety remember that 0 is how you normally feel, 50 is as anxious as you can imagine ever being and -50 is as non-anxious as you can imagine ever being. Give me a number now and I'll write it down. Ok, now please give me a number on the scale for relaxation. Remember that 0 is how relaxed you normally feel, 50 is as non-relaxed or as tense as you can imagine being and -50 is as relaxed as you can ever ever feel that you might be. Give me a number now and I'll write it down.

25.10 mins

Thankyou. Now relaxing deeper and deeper into hypnosis with your eyes open I'm going to show you a film. You can stay deeply relaxed and deeply hypnotised whilst you watch the film. Nothing that you see or hear needs to bother or disturb you in any way you can stay completely calm completely comfortable and completely relaxed. Nothing needs to bother you or disturb you nothing needs to make you anxious. Anything that bothers you can just drift away into the background and you can stay just as calm, just as relaxed and just as comfortable as you are right now. You can concentrate on listening to the sound of my voice or drift back to your special place all the time feeling calm, comfortable and completely relaxed.

And remember that anything you see or hear doesn't need to bother or disturb you in any way, you can stay completely calm completely comfortable and totally relaxed.

Remember that nothing you see or hear needs to bother you or disturb you. Just stay completely calm and relaxed.

Even the noises you can hear can just fade away into the background fade right away, just concentrate on the sound of my voice staying totally calm completely controlled and completely relaxed.

So calm, so comfortable nothing to bother or disturb you nothing that you see or hear just staying so calm so relaxed

Even the noise of the drill does not need to disturb you at all you can just stay just as relaxed as you are

And if you need to, you can just go back to your special place staying completely calm controlled and relaxed just enjoying those feelings enjoying the fact that and enjoying staying completely relaxed Everything you can see and hear can fade into the background Now I'm going to ask you how watching the film made you feel. Now please give me a number on the scale for anxiety. Remember that 0 is how you normally feel, 50 is as anxious as you can imagine ever being and -50 is as non-anxious as you can imagine ever being. Give me a number now and I'll write it down.

Ok, now give me a number on the scale for relaxation. Remember that 0 is how relaxed you normally feel, 50 is as non- relaxed or tense as you can imagine being and -50 is as relaxed as you can ever ever feel that you might be. Give me a number now and I'll write it down.

Just staying really calm and relaxed knowing that in a moment you're gonna coming back to the here and now bringing back with you all the calmness and control you need to face the rest of the day

In a moment I'm gonna count from 5 to 1, and on 5 you can remain just as relaxed as you are now. And then bit by bit with each number you can become more and more awake and alert. Feeling refreshed and comfortable, as if you've just had a really good night's sleep. And you can bring back with you all the calmness and the comfort that you've felt today,

Ok, so...

5, starting to wake and come back to the here and now. 4 becoming more alert, bringing back with you the knowledge and ability to remain completely calm, completely comfortable and completely relaxed, 3, 2, and 1 wide awake and refreshed, ready for the rest of the day.

# Appendix 5 Protocol for Hypnosis Alone Versus Hypnosis Plus Nitrous Oxide Inhalation Sedation to Reduce Experimental Dental Anxiety

## Protocol

Title:

Hypnosis Alone Versus Hypnosis Plus Nitrous Oxide Inhalation Sedation to Reduce Experimental Dental Anxiety.

## **Sponsors:**

University of Manchester

#### Aims:

To investigate any effect of the addition of Nitrous Oxide/Oxygen sedation to hypnosis on experimentally induced anxiety.

## **Objectives:**

To measure any effect on state anxiety with the addition of inhalation sedation with a fixed concentration of nitrous oxide to specific tape recorded hypnotic suggestion in healthy human volunteers.

To measure any effect of Inhalation Sedation with a fixed concentration of nitrous oxide on self-reported hypnotic depth.

#### **Background:**

An expert working party report was prepared for the Standing Dental Advisory Committee of the Department of Health in 1990 chaired by Professor Poswillo. This report considered the need for the use of general anaesthesia and sedation in dentistry outside hospitals and to develop guidelines for their safe use. The report criticised the existing definitions of sedation on the grounds that it failed to emphasise the essential basic element of hypnotic suggestion and reassurance and emphasised central nervous system depression rather than mood alteration. It made the principle recommendation that:

Simple dental sedation be defined as "A carefully controlled technique in which a single intravenous drug or a combination of oxygen and nitrous oxide, is used **to reinforce hypnotic suggestion and reassurance** in a way which allows dental treatment to be performed with minimal physiological and psychological stress, but which allows verbal contact with the patient to be maintained at all times, The technique must carry a margin of safety wide enough to render unintended loss of consciousness unlikely." (Poswillo, 1990) (emphasis added). Despite the above recommendation, the later definitions revert to the earlier definition and omit the importance of reassurance and hypnotic suggestion. Conscious sedation is defined by the GDC as:

A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of

sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely.

Section 4.11(*Maintaining Standards*, *Guidance for Dentists on Professional* and Personal Conduct, 2001).

Hypnosis has been investigated as a method of reducing anxiety before and during (Eitner et al., 2006) dental procedures, both 'live' (Eitner et al., 2006) and tape recorded (Ghoneim, Block, Sarasin, Davis, & Marchman, 2000; Hermes, Truebger, Hakim, & Sieg, 2005) as well as to treat and rehabilitate avoidant anxious patients (Moore, Abrahamsen, & Brodsgaard, 1996; Moore, Brodsgaard, & Abrahamsen, 2002).

There is a general acceptance of the fact that suggestion, hypnotic or semihypnotic is important in the success of inhalation sedation techniques using nitrous oxide/oxygen mixtures (Roberts, 1990). However, little systematic investigation of the relationship between hypnosis and Inhalation Sedation has been reported in the literature and evidence for the importance of hypnotic techniques is limited to case reports and case series (Shaw & Welbury, 1996). Work has been carried out showing that the effects of nitrous oxide/oxygen mixtures on pain perception can be altered by giving information designed to increase expectations about its effects (Dworkin, Chen, Shubert, & Clark, 1984; Dworkin, Chen, Leresche, & Clark, 1983). Expectancy of this sort has also been shown to be important in hypnotic responding (Wickless & Kirsch, 1989). In addition, pain has been shown to provoke more anxiety in a dental surgery setting and that volunteers in the dental setting had lower pain threshold and pain tolerance than those in a laboratory setting (Dworkin & Chen, 1982).

Previous experiments have been carried out which aimed to investigate the addition of hypnosis to sedation with nitrous oxide the results of which are being analysed, but despite increases in relaxation, anxiety produced by watching a film was no more reduced than with nitrous oxide alone. Some research has suggested that inhalation sedation with nitrous oxide (IHS) can affect hypnotic performance. An early paper investigated the effect of nitrous oxide on the acceptance of hypnotic suggestions in volunteers and concluded that nitrous oxide/ oxygen mixtures increased the likelihood of suggestions being responded to (Barber, Donaldson, Ramras, & Allen, 1979), but the study was small, and only 3 suggestions were presented. In addition, IHS has been shown to increase imaginative ability and suggestibility (Whalley & Brooks, 2009).

One potential explanation for increase in hypnotic performance with IHS is that the experience of sedation has long been considered similar to the feeling of being hypnotised (Bingham, 1964; Carnow, 1972) so it would be important to measure how hypnotised people feel during the combined hypnosis and IHS procedures compared to hypnosis alone.

If it can be shown that IHS increases the effects of hypnosis on anxiety in a dental context, this could allow clinicians to more successfully use hypnosis with their anxious patients.

#### The present study

Because of the lack of previous studies it is not ethical to use a sample of dentally anxious patients at this stage; therefore normal volunteers will be recruited for this study. Although they will not exhibit severe dental anxiety, even non anxious individuals show increased anxiety in the dental setting (Dworkin & Chen, 1982).

In addition, films have been used to produce basic emotions in psychological research (Hewig et al., 2005) and these have been shown to produce a modest rise in anxiety levels (Santagostino, Amoretti, Frattini, Zerbi, & et al., 1996). One such film is Marathon man (Paramount Pictures 1976). This depicts torture by probing then drilling teeth without anaesthesia and has been shown to elicit the emotions of fear and disgust in a previous study (Hewig et al., 2005). This film was piloted in a previous study, and found not to produce sufficient anxiety in the volunteers. A new film was therefore developed using small excerpts from *Marathon Man* together with excerpts from two commercially released horror films, The *Dentist* (Trimark Pictures Inc.1996) and *The Dentist 2* (Trimark Pictures Inc.1998). This film produces reliable increases in self-reported anxiety levels.

Volunteer participants will be randomised into two groups, hypnotic suggestion alone (with placebo IHS – air plus oxygen) and nitrous oxide/oxygen IHS with hypnotic suggestion. Both groups will watch the anxiety provoking film, and their state anxiety and relaxation level will be compared to baseline levels

before the start of the experiment, after hypnotic induction, after the hypnotic

intervention and after the completion of the experiment.

## Methods:

## **Study Design**

The study will be a single blind, between subjects, two group, randomised

design. The independent variable will be intervention condition (IHS plus

hypnosis vs. oxygen inhalation plus hypnosis). As such, the test conditions will

be:

- 1. Audio-recorded hypnosis (a hypnotic induction procedure, with specific hypnotic suggestions for reduced anxiety and anxiety control) delivered with mock Inhalation Sedation using pure oxygen in a clinical protocol which mimics true IHS, (control condition)
- 2. Audio recorded hypnotic induction procedure, with specific hypnotic suggestions for reduced anxiety and anxiety control paired with Inhalation sedation with nitrous oxide to a maximum concentration of 25% (experimental condition).

The dependent variables will be: Scores on an anxiety scale, ranging from -100 to +100 where -100 is as non-anxious as the person can imagine ever being, 0 is how they normally feel and 100 is as anxious or fearful as the person can imagine ever being, and a relaxation scale ranging from -100 to +100 where - 100 is as relaxed as the person can imagine ever being, 0 is how they normally feel and 100 is as tense or non-relaxed as the person can imagine ever being. In addition, hypnotic depth will be measured using the Tart hypnotic depth scale (Tart, 1970).

Dental trait anxiety will be measured using the MDAS (Humphris, Morrison, & Lindsay, 1995) and scores will be analysed to identify any relationship between

trait dental anxiety and anxiety levels during the experiment. General trait anxiety as measured by the trait scale of the Spielberger State-Trait Anxiety Inventory (Spielberger, 1983) will also be used in this way.

#### **Hypotheses**

H0: That the change in anxiety levels in the hypnotic suggestion and oxygen group from pre-film to post-film will be equal to the change in anxiety levels in the nitrous oxide plus hypnotic suggestion group.

H0: that there will be no difference in the level of hypnotic depth reported between the groups.

#### Setting

The initial questionnaires; STAI-trait and the MDAS together with a standard hospital medical history form will be administered in online (i.e. not in a dental environment)

The test setting will be a surgery in the oral surgery department at Manchester Dental Hospital equipped with a computer and a portable inhalation sedation machine.

#### **Participants**

Volunteers will be sought who do not consider themselves to be dentally phobic.

They will be paid for their inconvenience and travel. The volunteers will be recruited by advertising via student research volunteering website at the University of Manchester. Volunteers will be excluded if they have a pre-existing psychological condition and if they score 20 or above on the MDAS (this may indicate dental phobia). In addition, volunteers will be medically fit and well (ASA I or II (Malamed, 1995)

#### Randomisation

A randomisation code will be computer generated. Allocation concealment will

be sealed envelopes containing the individual code numbers and opened by a

research nurse.

#### Sample size

A sample size calculation will be carried out based on the results of the

previous study which investigated the effects of the addition of hypnotic

suggestion to inhalation sedation. This study used a sample size of 60

participants (30 in each group)

## Materials

## Questionnaires

- 1. Modified Dental Anxiety Scale (Humphris, Freeman, Campbell, Tuutti, & D'Souza, 2000; Humphris et al., 1995)
- Trait portion of the Spielberger State Trait Anxiety Inventory (Spielberger, 1983)
- 3. Scores on an anxiety scale, ranging from -100 to +100 where -100 is as non-anxious as the person can imagine ever being, 0 is how they normally feel and 100 is as anxious or fearful as the person can imagine ever being. Relaxation scale ranging from -100 to +100 where -100 is as relaxed as the person can imagine ever being, 0 is how they normally feel and 100 is as tense or non-relaxed as the person can imagine ever being. Hypnotic depth will be measured using the Tart hypnotic depth scale (Tart, 1970).
- 4. Manchester Dental Hospital standard medical history form.

## Equipment

- 1. Standard inhalation sedation machine. This will be subject to standard safety checks before use which are laid down in the health and safety regulations of the Dental Hospital.
- 2. Laptop computer with DVD player

## **Outcome Measures:**

Scores on an anxiety scale, ranging from -100 to +100 where -100 is as non-

anxious as the person can imagine ever being, 0 is how they normally feel and

100 is as anxious or fearful as the person can imagine ever being.

Relaxation scale ranging from -100 to +100 where -100 is as relaxed as the

person can imagine ever being, 0 is how they normally feel and 100 is as tense

or non-relaxed as the person can imagine ever being.

Hypnotic depth will be measured using the Tart hypnotic depth scale (Tart,

1970).

Participants will be asked to indicate if they believe that they have received nitrous oxide sedation or oxygen.

## **Outline Procedure**

Two separate groups, randomly allocated

25% Nitrous oxide inhalation sedation + hypnotic suggestion

Mock inhalation sedation (pure oxygen) + hypnotic suggestion

Interventions identical and recorded to ensure reproducibility

Blinding – participants will be blind to group, as the mock inhalation sedation procedure will be identical to the sedation procedure. The experimenter cannot

be blind to the group as they will administer the nitrous oxide mixture or oxygen in the control condition. This should not introduce bias, as the intervention (hypnosis and information to the participant on the administration of nitrous oxide will be administered on DVD through headphones so the experimenter is unable to influence this. It is important that the experimenter is aware of the sedation status of the participant so that they can be appropriately monitored.

#### Procedure

Volunteers will be informed that they will be taking part in an experiment to see if nitrous oxide/oxygen mixtures combined with hypnosis reduces anxiety in a dental setting. They will be reassured that no dental treatment will be carried out, but that they will be required to watch a film clip depicting extremely unpleasant dental procedures. Their medical history will be checked against the information they have provided and any changes noted. Participants whose medical status has changed may be excluded from the study. Participants suffering from colds or blocked noses will be excluded, but may return at a later date if they wish.

The information leaflet will provide information on the actions of nitrous oxide, describing it as a commonly used method of allowing anxious patients to receive dental treatment and describing some of the sensations they may feel when breathing the gas and air mixture. This is based on Dworkin et al's script for high information condition which showed greater effects than the low information group (S. Dworkin et al., 1984). In addition, the information leaflet will explain hypnosis as a procedure that anyone can experience that is generally pleasant and relaxing. This information is based on the British Psychological society report on the nature of hypnosis (*The Nature of Hypnosis*, 2001).

All participants will be informed that they may withdraw from the experiment at any time without giving a reason.

Participants will sign a consent form when they attend for the experiment. The trait section of the State Trait Anxiety Inventory and the modified DAS will be completed by all participants online before attending for the experiment. Participants will attend for the experiment and will be seated comfortably in the chair. They will complete the anxiety and relaxation scales. The IHS nasal hood placed on the nose ensuring there are no leaks. The headphones will be placed and the recording started. The recording will commence a hypnotic induction procedure based on breathing and progressive muscular relaxation,

incorporating information that nitrous oxide will be given and the concentration increased at specific times.

The experimenter will introduce the  $N_2O$  or fake doing so, using oxygen only according to a timed sequence: 100% oxygen for one minute, 10% nitrous oxide for 2 minutes, 20% nitrous oxide for 2 minutes, finally 25% nitrous oxide. The experimenter will monitor the patient visually to ensure that they are not over-sedated. Following this at the end of the hypnotic induction measures on the scales will be taken as before, and a report of hypnotic depth given.

The hypnotic induction will be followed by specific suggestions of comfort, lack of anxious thoughts and feelings and control over any anxious thoughts and feelings they may experience and a post hypnotic suggestion that this will continue throughout the remainder of the experiment. The recording will last about 30 minutes. Following the end of the recording participants will be informed that they can remain just as relaxed as they are now and complete the anxiety and relaxation scales and the hypnotic depth scale then watch a film clip. The nitrous oxide/oxygen or oxygen only mixture will remain flowing and continual hypnotic suggestion given throughout the film. They will then watch the film clip and complete the scales as previously.

Following the completion of these, participants will be told that all bodily sensations will shortly return to normal and hypnotic alerting will follow whilst 100% oxygen is given for at least 2 minutes. The experimenter will check that the participant is fully alert and awake and that all bodily sensations have returned to normal before disconnecting the IHS machine. The participant will complete final scale measures and asked whether they thought they had received nitrous oxide or oxygen.

Participants will be debriefed in the chair and allowed to leave when they are considered to be recovered. They will have the opportunity to discuss their experience and report any problems they felt and be provided with a telephone and email contact in case of any later effects from the experiment. During the experiment, any adverse reaction to the nitrous oxide/oxygen sedation will result in the experiment being terminated and the patient

recovered by the administration of 100% oxygen using standard dental hospital protocols. These reactions are very rare and usually mild involving feelings of or even more rarely actual nausea. Adverse reactions to hypnosis are similarly rare, but will be managed by reassurance, reversal of sedation and arousal from hypnosis at the appropriate time, followed by careful debriefing.

#### **Statistical Analysis**

Providing that the assumptions of normality are met by the data, scores on the anxiety, relaxation and hypnotic depth scales will be compared using a one-way ANCOVA comparing post-intervention anxiety across the two conditions, controlling for pre-intervention anxiety and potentially MDAS scores. Self-reported hypnotic depth will be analysed similarly. Scores on the MDAS and STAI-T scales will be analysed to investigate correlations between them and any changes in anxiety levels. If the data are not normally distributed, non-parametric tests will be used (Freidman's ANOVA). Data will be analysed using SPSS 16.0

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## Appendix 6

## List of Abbreviations used in the text

AZI	A German Language dental fear questionnaire
BP	Blood Pressure
BPd	Diastolic Blood Pressure
BPs	Systolic Blood Pressure
BT	Behavioural Therapy
CBT	Cognitive Behavioural Treatment
DAQ	Dental Anxiety Question
DAS	Dental Anxiety Scale
DBS	Dental Beliefs Survey
DCQ	Dental Cognitions Questionnaire
DFS	Dental Fear Survey
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders Published by American Psychiatric Association
DSR	Dental Situation Reactions
EEG	Electroencephalographic Recordings
EMG	Electromyograms
fMRI	Functional Magnetic Resonance Imaging
GA	General Anaesthesia
GDP	General Dental Practitioner
GFS	Geer Fear Scale
HAQ	Hierarchical Anxiety Questionnaire

HR	Heart Rate
IHS	Inhalation Sedation
IV sedation	Intravenous Sedation
MACL	Mood Adjective Check List
MDAS	Modified Dental Anxiety Scale
MIP	Mood Induction Procedure
N <sub>2</sub> O	Nitrous Oxide
RCT	Randomised Controlled Clinical Trial
RR	Respiration Rate
SCR and SR	Skin Conductance Response and Skin Resistance
SpO2	Oxygen Saturation
STAI	Stait Trait Anxiety Inventory
STAI(S)	State Scale of the STAI
STAI(T)	Trait Scale of the STAI
SUDs scale	Subjective Units of Distress Scale
VAS	Visual Analogue Scale