**The effect of an acclimatization visit on children’s behaviour during inhalational sedation in a United Arab Emirates paediatric dentistry postgraduate setting**

Mawlood Kowash1, Jinous F Tahmassebi2, Mohammad M. Abdo1, Manal Al Halabi1, Iyad Hussein1, Anas AlSalami1, Amar Hassan1, Yrsa Sverrisdottir3

1Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine & Health Sciences, Dubai, United Arab Emirates

2Leeds Dental Institute, Leeds University, UK

3College of Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates

**Corresponding author**

Mawlood Kowash
Hamdan Bin Mohammed College of Dental Medicine

Mohammed Bin Rashid University of Medicine & Health Sciences

P.O. Box 505055, Dubai

United Arab Emirates

Tel: +97143838908

Email: Mawlood.kowash@mbru.ac.ae

**ABSTRACT**

**Background:** Inhalation sedation is a proven safe method for reducing children’s dental anxiety and has been used worldwide for decades. It is a light form of sedation and is a mixture of nitrous oxide and oxygen breathed through a nosepiece. This helps the child to feel relaxed and accept treatment. Rather than starting the sedation at the first dental visit, many clinicians suggest an acclimatization/familiarization visit.

There is controversy regarding the use of acclimatization visits for dental sedation treatment pathways for children. The acclimatization visit can be defined as “one in which sedation only is provided and no, or minimal dental treatment, is carried out”. This may increase acceptance based on desensitization and acclimatization principles underpinning many behaviour management techniques. This study aims to identify whether, an inhalation sedation acclimatization visit is effective in making anxious children more relaxed and accepting of dental treatment, or not.

**Methods:** The proposed study is a single-center, single blind (to the dentist providing dental treatment), parallel group randomized controlled two arm superiority trial. Sixty paediatric patients aged 5-15 years attending the Postgraduate Paediatrc Clinic at the Hamdan Bin Mohammed College of Dental Medicine. The participants will be allocated randomly and equally to either: 1) Study Group: children and parents would attend a visit for prevention and inhalation sedation will be introduced and tried; 2) Control Group: children and parents would attend for prevention visit and discussion of inhalation sedation only. At the initial visit the sedation need score will be recorded using the Paediatric Indicator of Sedation Need (p-SION). As a component of p-SION it will include anxiety measure using the Modified Dental Anxiety Scale (MDAS). Treatment for both groups will commence at 2nd visit and the following outcomes will be recorded: Completion of dental treatment; Anxiety Scores at baseline and after treatment using MDAS, Frankl rating behaviour scale and Physiological anxiety related changes will be recorded using E4 wrist bands.

**Significance:** The findings of this research will provide evidence on whether or not to have a separate session for acclimatization for children requiring dental treatment under inhalation sedation.

**Keywords:** Inhalation sedation; Anxiety; Acclimatization; dental treatment

**TRIAL REGISTRATION DATA SET: ISRCTN REGISTRY**

|  |  |
| --- | --- |
| Primary registry and trial identifying number  | ISRCTN registry  |
| Date of registration in primary registry  | Pending  |
| Secondary identifying numbers  | Not applicable |
| Source(s) of monetary or material support  | Hamdan Bin Mohammed College of Dental Medicine (HBMCDM), Mohammed Bin Rashid University of Medicine and Health Sciences (MBRU) |
| Primary sponsor | Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences |
| Contact for public queries  | Dr. Mawlood Kowash, Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine & Health Sciences, Dubai Healthcare City, Dubai, UAEEmail: Mawlood.kowash@mbru.ac.aeTel: +97143838908 |
| Contact for scientific queries | Dr. Mawlood Kowash, Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine & Health Sciences, Dubai Healthcare City, Dubai, UAEEmail: Mawlood.kowash@mbru.ac.aeTel: +97143838908 |
| Public title  | The effect of an inhalational sedation familiarization visit on children’s dental behaviour  |
| Scientific title | A single centre investigator blinded randomized parallel group study to investigate the effect of an acclimatization visit on children’s behaviour during inhalational sedation in a United Arab Emirates paediatric dentistry postgraduate setting  |
| Country of recruitment | United Arab Emirates (UAE) |
| Health condition(s) or problem(s) studied | Dental anxiety in paediatric patients undergoing dental treatment under nitrous oxide inhalation sedation |
| Interventions | The effect of an acclimatisation visit of 15 minutes nitrous oxide inhalation sedation together with regular verbal explanation versus regular explanation alone on child’s behaviour and acceptance of dental treatment under nitrous oxide inhalation sedation. |
| Key inclusion and exclusion criteria | **Inclusion criteria*** Healthy children aged 5-15years in need of dental treatment under inhalation sedation, (ASA I&II)
* No learning disabilities
* Suitable for nitrous oxide/oxygen inhalation sedation (IHS)
* UAE and non-UAE nationals’ parents and children will be eligible to participate in the study.

**Exclusion criteria:** * Children with special healthcare needs and/or medically compromised.
* Children whose parents refuse to consent.
* Those with complex medical histories ASA III and ASA IV
* Children with a known diagnosed psychiatric disorder
* Children younger than five years and older than 15 years.
 |
| Study type | Single-centre, single blind (to dentist providing treatment), parallel group randomized controlled two arm clinical trial |
| Date of first enrolment | Pending  |
| Target sample size | 60 |
| Recruitment status | Recruiting  |
| Primary outcome  | Improved child’s behaviour and cooperation during dental treatment |
| Key secondary outcomes | 1. Satisfactory completion of the required dental treatment within reasonable time
2. Children’s and parents’ acceptance of dental treatment with or without acclimatization visit.
3. Suitability of the Indicator of Sedation Need (IOSN) as a useful tool to predict the UAE child patients who would benefit from inhalation sedation.
 |

**PROTOCOL VERSION**

Issue date: March 2019; Protocol version 001

Authors: MK, JT, MMA, MA, IH, AS, YS

**ROLES AND RESPONSIBILITIES**

**Authors’ contributions:** MK, JT conceived the study and initiated its design. MK, JT, MMA, MA, IH will be involved in study implementation. AH provided statistical expertise in clinical trial design and will conduct the statistical analysis. YS will provide expertise with physiological data interpretation. All authors contributed to finalizing the study protocol and approved the final manuscript.

**Sponsor contact information:** Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Building 34, Dubai Healthcare City, PO Box 505055, Dubai, United Arab Emirates.

Tel: +971 (0)4 383 8937; Email: reena.john@mbru.ac.ae

**DATA STATEMENT:** Data from this study will be deposited in a data repository

**CONFLICTS OF INTEREST:** None of the authors have any conflict of interest to declare

**ACKNOWLEDGEMENTS:**

**Funding:** The study is fully funded by internal research grant from the Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences (Grant # MBRU-IRB-2018-014).

 **Sponsor and funder roles:** Sponsor and funder did not have any role in the study design. The implementation of the study design, data analysis, data interpretation and submission of results for publication will be carried out entirely independent of the sponsor and funder.

**COMMITTEES:**

**Steering committee:** All authors listed in the title page are members of the steering committee responsible for the following:

1. Finalizing and agreeing on the final protocol and data collection forms
2. Reviewing study progress and ensure the smooth running according to the protocol
3. Agree to any necessary changes in the study protocol
4. Prepare, revise and approve manuscript for publication

**Principal investigator, research clinicians and administrative staff:** This team will be responsible for continuous management of the study according to the protocol and oversee patient recruitment, examination, provision of intervention material (nitrous oxide sedation) and follow-up.

**Data management committee:** This will comprise of the PI, administrative staff and the study statistician (AH). This team will be responsible for data entry and verification as well as ensure that collected data is stored securely.

**INTRODUCTION
Background and rationale**

The paediatric dentist uses a wide variety of techniques to allay the fears of children to increase their cooperation while receiving dental treatment. These include symbolic modelling, desensitization, tell-show-do, visual imagery, and familiarization. When these techniques fail, other treatment modalities such as sedation and general anaesthesia must be attempted according to the American Academy of Pediatric Dentistry (AAPD, 2015). Dental caries is the most common reason a child between five and nine years of age is admitted to hospital in both England and Scotland (30.9% of all General Anaesthesia-GAs) and these figures are increasing every year, as are the average numbers of teeth removed, according to Royal College of Surgeons of England (Health and Social Care Information Centre 2014). These admissions are reported to be clearly associated with very significant morbidity and are not without the risk of mortality (Bridgman et al. 1999; Department of Health, 2000). In addition, the cost of GA hospital admissions is very expensive. For example, in England it was £30 million in 2012–2013 (Department of Health 2013).

Deery (2015) reported a recent study from the north-west of England which showed that

repeat GA rates ranging from 12 to 37%. However, when children were appropriately assessed by a consultant in paediatric dentistry, the result of a recent audit in Sheffield showed GA repeat rate of less than 1%.

In Dubai and certainly in all UAE the level of dental caries in children is very high (Alayyan et al, 2017). As far as we are aware, there are no data on numbers of dental GAs in the UAE and their repeat rate. However, from our clinical experience both frequency of GA and repeat rate are high especially in Abu Dhabi emirate.

**Assessment of anxiety in children:**

Coulthard and co-workers (2011) developed an Indicator of Sedation Need (IOSN). The IOSN is a tool-as its name indicate to be used to assess the need for sedation. The IOSN can be used as a tool to help clinicians to make a decision about referring adult patients to have sedation for their dental treatment. IOSN is composed of three components; one of which is the **anxiety component** which uses the Modified Dental Anxiety Scale (MDAS) and is completed by the patient. This scale is specifically designed for adults, although a child MDAS is available (McDonnell-Boudra et al 2014). The second component of IOSN is **medical status** which is based on the patient’s American Society of Anesthesiologists (ASA) class. The last component is the **treatment complexity** and again, the indicative list of treatment provided is based on treatment offered to adults. The latter two components are completed by the clinician. (See Tables 1 and 2)

Recently Madouh and Tahmassebi (2016) piloted a paediatric version (p-IOSN) in Leeds children, UK. They used two anxiety questionnaires; The Facial Image Scale (FIS) was used for children under 10 years of age and the faces version of the Modified Child Dental Anxiety Scale (MCDASf) for older children (Howard and Freeman 2007). They also modified the last component of the IOSN which is the “treatment complexity” in order that it would be applicable to children’s treatment rather than adults. (See Table 3)

**Inhalation sedation (IHS)**: is a light form of sedation. It is a mixture of nitrous oxide and oxygen breathed through a nosepiece. This helps the child to feel relaxed and accept treatment.

There is controversy regarding the use of acclimatization (familiarization) visits for dental sedation treatment pathways for children. The acclimatization visit can be defined as one in which sedation only is provided and no, or minimal dental intervention, is carried out. On the one hand it may increase acceptance based on desensitization and acclimatization principles underpinning many behaviour management techniques. On the other hand, it exposes the child to a pharmaceutical intervention and increases contact time which may have an effect on patient compliance.

**Objectives**

**Research Hypothesis:** Children’s behaviors and anxiety levels are better in the study group, compared to those in the control group, who will not be offered a familiarization visit and managed routinely.

**Primary objective:** To compare the effect a 15-minutes Nitrous oxide sedation acclimatization (familiarization) visit prior to routine inhalation sedation treatment visit on children’s behavior and anxiety level.

**Secondary objectives:**

1. To compare the effect of a 15-minutes Nitrous oxide sedation familiarization visit prior to routine inhalation sedation treatment visit versus inhalation sedation treatment visit without familiarization visit on the following parameters in patients undergoing dental treatment under inhalation sedation:
2. Satisfactory completion of the required dental treatment within reasonable time
3. children’s and parental acceptance of dental treatment with or without

 acclimatization visit.

1. To test the Paediatric Indicator of Sedation Need (p-IOSN) as a useful tool to predict the UAE child patients who would benefit from inhalation sedation.

**METHODS**

**Trial design**

The proposed study is a single-center, single blind (to the dentist providing dental treatment), parallel group randomized controlled two arm superiority trial, adhering to the guidelines of the American Dental Association (American Dental Association, 2012) and The CONSORT Group (Lee, 2014). Ethical approval for the study has been granted by the Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences Institutional Review Board (Reference: Grant # MBRU-IRB-2018-014).

**Sample size calculation:** The study is sized to have an 80% power to detect a statistically significant difference in children behavior and anxiety level between the study and control groups. The sample size calculations used α=0.05 for a 2-sided test and data from earlier similar studies (Badalaty et al., 1990 and Al-Zahrani et al., 2009). The number of participants required is 60 (30 in each group). To compensate for dropout rate of approximately 20%, a total of 70 participants will be recruited for both arms.

**PARTICIPANTS, INTERVENTIONS, AND OUTCOMES**

**Study setting:** All the parents of children aged 5-15 years who will be referred for paediatric specialist treatment in Dubai Dental Hospital in need of treatment under inhalation sedation within six months’ period will be invited to participate in the study.

**Eligibility criteria**

Inclusion criteria

* Healthy children aged 5-15years in need of dental treatment under inhalation sedation
* No learning disabilities
* Suitable for nitrous oxide/oxygen inhalation sedation (IHS)
* UAE and non-UAE nationals’ parents and children will be eligible to participate in the study.

Exclusion Criteria

* Children with special healthcare needs and/or medically compromised.
* Children who their parents refuse to consent.
* Those with complex medical histories ASA III and ASA IV
* Children with a known diagnosed psychiatric disorder
* Children younger than five years and older than 15 years.

**Ethical considerations:** All parents/caregivers and children fulfilling the inclusion criteria will be eligible for participation. In addition, to a routine verbal and written information and treatment consent form signed by parent/caregiver of the child prior to treatment under inhalation sedation, participating children’s parents/caregivers will be informed verbally and on writing about the study. Participants and their parents/guardians will be appropriately informed about the objectives of the study; each participant will be ensured anonymity. Following data analysis, collective results will be published, we will never publish individual scores. A signed, informed consent form will be required for participation from the parents/caregivers

**Interventions:** After baseline examination by the clinical team, eligibility verification, participant’s assent and parents’/guardian’s consent submission, participants will be randomized to the two study groups (30 patients per group). Block randomization with a 1:1 allocation will be performed by the PI with the aid of a computer program and help of biostatistician (AH), to either study or control group:

1. **Study Group.**  Families (children and parents) would attend a visit for prevention and inhalation sedation will be introduced and tried.
2. **Control** **Group**. Families would attend for prevention visit and discussion of inhalation sedation only.

At the initial visit the sedation need score will be recorded using the Pediatric Indicator of Sedation Need (p-SION). As a component of p-SION it will include anxiety measure using the Modified Dental Anxiety Scale (MDAS) (Table 1).

Treatment for both groups will commence at 2nd visit and the following outcomes will be recorded (Tables 1 – 4):

1. Completion of dental treatment
2. Anxiety Scores at baseline and after treatment using MDAS at different time points and Physiological anxiety related changes will be recorded using **E4 wrist bands**

The wrist band will be placed 15 minutes before the patient comes into the surgery for treatment and will be taken off 15 minutes after the completion of treatment. This will

enable recording physiological parameters continuously before, during and after the dental treatment. E4 Wrist bands will provide Electrodermal Activity (EDA) also known as Galvanic Skin Response (GSR), Blood Volume Pulse (BVP), Acceleration, Heart Rate (HR), and Temperature. E4 wrist bands are small, very similar to wearing a watch and we do not anticipate any increase in anxiety in children as a result of wearing these wrist bands.

The E4 wrist band was approved by U.S. Food and Drug Administration as a medical device. It is used in a wide range of research settings with configurations for palmar skin conductance measurement or the use of gelled electrodes secured under the band.  For more information about E4 wrist band, please refer to the link below:

<https://store.empatica.com/products/e4-wristband?variant=39588207747>

1. Behaviour score during treatment (Frankl score). (Table 4).

The anxiety scale that is part of the p-IOSN, MCDASf has been validated for this

age group in many previous studies. It has also been used both in English and Arabic (translated into Arabic and back translated in English) already here in the UAE. *We quote our own Algharebi et al 2018 (Abstract accepted in the British Society of Paediatric Dentistry Sep 2018). UAE Children’s Dental Anxiety (Self and Proxy Reported) and their Dental Behaviour. Another study conducted in the UAE by Hawamdeh* and Awad (2013).

**Parental/Children’s satisfaction and acceptance questionnaire**

Parents and children will be requested to complete a short questionnaire (Appendix II) to measure their acceptance/satisfaction of dental treatment with or without acclimatization visit.

*Statistical analysis*: Data analysis will be conducted, after investigating distribution normality, with the appropriate parametric or not parametric statistical tests and the statistical software SPSS™ 24.0.0 (©SPSS Inc., USA). The level of significance will be set α=0.05.

Use of Descriptive statistics and quantitative data will be analysed using means and standard deviations if normally distributed or medians and interquartile range if skewed. Mean changes of anxiety scores and corresponding 95% confidence intervals will be determined to compare the two treatments (sedation with familiarisation and sedation without familiarisation). T tests will be used to compare quantitative data if normally distributed or Mann Whitney U test if skewed. The Chi square test will be used to investigate association of categorical data. Box plots, individual and mean profiles of anxiety scores at each assessment time point for each treatment will be produced.

*Primary outcome measure:* Statistically significant improvement in behavior and anxiety levels as measured physiologically be the E4 wrist band and by comparing Anxiety Scores at baseline and after treatment using MDAS at different time points.

 *Secondary outcome measure:* The following statistically significant outcomes will be classified as evidence of beneficial effect of the acclimatization inhalation sedation visit: satisfactory completion of the required dental treatment and children’s and parents’ acceptance of dental treatment with or without acclimatization visit.

**DATA MANAGEMENT**

Each participant will be assigned a unique study code number. Participant identifiers which will be collected include name, phone number and clinic file number. The list connecting the participant name/contact details with the study code number will be kept in a locked cabinet in the PI's office. Only the PI will have access to this list. Clinical recording sheets, questionnaires and E4 wrist band physiological data will only be labelled using the code number. When the study is completed, and the data have been analyzed, the list will be destroyed. No personal information will be used in any report or publication.

**DISCUSSION**

The American Academy of Paediatric Dentistry (AAPD) recognizes nitrous oxide/oxygen inhalation as a safe and effective technique to reduce anxiety, produce analgesia, and enhance effective communication between a patient and health care provider (AAPD 2013).

The Scottish Dental Clinical Effectiveness Programme (SDCEP), June 2017 also recommended the use inhalation sedation with nitrous oxide/oxygen as the preferred technique for conscious sedation, unless judged to be unsuitable for the patient and clinical need and that “Inhalation sedation with nitrous oxide/oxygen is the only standard technique for children (Section 1.3).6,8”

There is paucity of data and controversy regarding the use of acclimatization (familiarization) visit for dental sedation treatment to help reduce anxiety and enhance the acceptance of dental treatment and cooperation of child dental patients. The SDCEP recommended the use of introductory (Acclimatization) visit and issued the following statement: “A brief trial of nitrous oxide/oxygen at the assessment appointment may be helpful for the psychological preparation of some children”.

The findings of this research will provide some evidence for the guidelines on whether or not to have a separate session for acclimatization for children requiring dental treatment under inhalation sedation. At present time the recommendations are based on expert opinions and are not evidence based.

Such an intervention if tested and approved to be successful will help many anxious children to be treated in the clinic and avoid dental GA, an option with significant morbidity and are not without the risk of mortality (Bridgman et al. 1999; Department of Health, 2000). In addition, it will reduce dental treatment cost by avoiding expensive GA hospital admissions (Department of Health 2013).

**References**

Alayyan W, Al Halabi M, Hussein I, Khamis A, Kowash M. A Systematic Review and Meta-analysis of School Children’s Caries Studies in Gulf Cooperation Council States. Journal of International Society of Preventive & Community Dentistry. 2017;7(5):234-241.

ALGHAREBI S, KOWASH M, HALABI M, KHAMIS A& HUSSEIN I. UAE Children’s Dental Anxiety (Self and Proxy Reported) and their Dental Behaviour. *Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, UAE.*

Badalaty et al. A comparison of chloral hydrate and diazepam sedation in young children. PEDIATRIC DENTISTRY: FEBRUARY, 1990 -- VOLUME 12, NUMBER 133

Bridgman CM, Ashby D, Holloway PJ. An investigation of the effects on children of tooth extraction under general anaesthesia in general dental practice. Br Dent J 1999; 186: 245–247.

Coulthard P, Bridgman C, Gough L, et al. Estimating the need for dental sedation. 1. The indicator of sedation need (IOSN)–a novel assessment tool. Br Dent J. 2011;211(5): E10.

Deery C. Dental caries in children and the level of repeat general anaesthetics for

dental extractions. A national disgrace. Dent Update. 2015: 305-306

Department of Health. A Conscious Decision: A Review of the Use of General Anaesthesia and Conscious Sedation in Primary Dental Care. London, UK: 2000.

Department of Health. Reference costs 2012–2013. London, UK: 2013.

Hawamdeh S, Awad M. Dental anxiety: Prevalence and associated factors. Eur J Gen Dent 2013; 2:270-3

Health and Social Care Information Centre. NHS Dental Statistics for England – 2013–2014. London, UK: 2014.

Houpt MI, Kupietzky A, Tofsky N, Koenigsberg S. Effects of nitrous oxide on diazepam sedation of young children. *Pediatric Dentistry* 1996; **18**: 236–41.

Howard K.Freeman R. Reliability and validity of a faces version of the Modified Child Dental Anxiety Scale. International Journal of Paediatric Dentistry. 2007: 17: 281–288.

Madouh1 M, Tahmassebi JF. Utilising a paediatric version of the indicator of sedation need for children’s dental care: a pilot study. Eur Arch Paediatr Dent (2016) 17:265–270.

McDonnell-Boudra D, Martin A, Hussein I. In vivo exposure therapy for the treatment of an adult needle phobic. Dent Update. 2014 ;41(6):533-540.

The American Academy of Pediatric Dentistry (AAPD). Guideline on Behavior Guidance for the Pediatric Dental Patient. REFERENCE MANUAL V 37 / NO 6 15 / 16: 18-193.

 **Table 1: Indicator of Sedation Need and Outcomes of Dental Treatment under Sedation**

|  |  |  |
| --- | --- | --- |
| IOSN Domain | Score |  Source |
| Anxiety | 1-3 | Based on MDAS score:MDAS between 5-11 is minimal anxiety, scores 1MDAS between 12-18 is moderate anxiety, scores 2MDAS between 19-25 is high anxiety, scores 3 |
| Medical history | 1-4 | A range of medical and behavioral indicators is provided; as a general rule, ASA class is utilized:ASA I, scores 1ASA II and/or strong gag reflex, scores 2 or 3 (depends on clinical judgment)ASA III, scores 4 |
| Treatment Complexity | 1-4 | An indicative list of treatments is provided. If the user of this tool is in doubt about the complexity of any given treatment they are asked to score high |
| IOSN metric | **IOSN description**  | **Sedation need?** |
| 3-4 | Minimal need for sedation  | No |
| 5-6 | Moderate need for sedation  | No  |
| 7-9 | High need for sedation | Yes  |
| 10-11 | Very high need for sedation | Yes  |
| Key:IOSN: Indicator of Sedation Need MDAS: Modified Dental Anxiety Scale Scale of the American Anesthesiologists classification of physical health: ASA I: Healthy ASA II: Mild Systemic Disease ASA III: Severe Systemic Disease (that does not pose a constant threat to life) |

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

**Table 2: Treatment complexity rank score for the pediatric version of the indicator of sedation need (p-IOSN)**

Table 3: Summary of p-IOSN scoring system modified for children

|  |  |  |
| --- | --- | --- |
| p-IOSN domain | Source | Score |
| Anxiety | **For 5 to 16 years old patients [Faces version of the Modified Child Dental Anxiety Scale (MCDASf)]:** |
| MCDASf  between 8-17 is minimal anxiety | 1 |
| MCDASf  between 18-28 is moderate anxiety | 2 |
| MCDASf  between 29-40 is high anxiety | 3 |
|  |  |
| Treatment complexity | Routine | 1 |
| Intermediate | 2 |
| Complex | 3 |
| High Complexity | 4 |
|  |  |
| Medical status | ASA I | 1 |
| ASA II and/or strong gag reflex (depends on clinical judgment) | 2-3 |
| ASA III | 4 |
|  |  |
| Total p-IOSN score | Anxiety score + treatment complexity score + Medical status score | 3-11 |
| p-IOSN: Paediatric version of the Indicator of Sedation Need FIS: Facial image scoreASA classification: American Society of Anesthesiologists classification of physical health: ASA I: Healthy ASA II: Mild Systemic Disease ASA III: Severe Systemic Disease (that does not pose a constant threat to life) |

**Table 4: Frankl Behavior Rating Scale**

|  |  |  |
| --- | --- | --- |
|  | FRANKL BEHAVIORAL RATING SCALE  |  |
| Rank  | **Description** |  |
| 1 - - | Definitely negative. Refusal of treatment, forceful crying, fearfulness, or any other overt evidence of extreme negativism. |  |
| 2 - | Negative. Reluctance to accept treatment, uncooperative, some evidence of negative attitude but not pronounced (sullen, withdrawn). |  |
| 3 + | Positive. Acceptance of treatment; cautious behavior at times; willingness to comply with the dentist, at times with reservation, but patient follows the dentist’s directions cooperatively. |  |
| 4 ++  | Definitely positive. Good rapport with the dentist, interest in the dental procedures, laughter and enjoyment. |  |

**Appendix II**

**Parent’s questionnaireإستبيان خاص بالأباء**

|  |  |
| --- | --- |
| **Statements****الإفادات (التعبير)** | **Response****الإجابة**  |
| **Strongly****agree****أوافق** **بشدة**  | **Agree****أوافق** | **No opinion****محايد** | **Disagree****أرفض** | **Disagree Strongly****أرفض بشدة** |
| The dentist explained very well why my child needed dental treatment.لقد قام طبيب الأسنان بشرح واف عن حاجة طفلي للعلاج. |  |  |  |  |  |
| I have no concerns about how the laughing gas sedation works.ليس لدي أي مخاوف تجاه ماهية عمل الغاز الضاحك. |  |  |  |  |  |
| I think the laughing gas sedation is doing a good job at helping my child to cope with the treatmentأعتقد بأن الغاز الضاحك يساعد في تقبل طفلي للعلاج. |  |  |  |  |  |
| My child coped well with having the laughing gas sedation.لقد تقبل طفلي العلاج بإستخدام الغاز الضاحك. |  |  |  |  |  |
| The dental team were kind and helpful during my child’s treatment.لقد كان فريق طب الأسنان لطيفا و خدوما خلال علاج الطفل.  |  |  |  |  |  |

 **Children’s Questionnaire**

**إسبيان خاص بالأطفال**

|  |  |
| --- | --- |
| **QUESTIONS****الأسئلة**  | **Response****الاجابة**  |
|  **Positive**  **ايجابي** http://1.bp.blogspot.com/-5Po5c6iNlt4/TiHvF2SxJzI/AAAAAAAABOk/Bfj--7Rxd9s/s1600/Funny+smiley+faces+cartoon+3.jpg | **Neutral****محايد** **https://encrypted-tbn2.gstatic.com/images?q=tbn:ANd9GcQYZDEgHiOfZsYOY21EhgC61oym9HaNIESzI-zLhoIfyYWkN9Ea** | **Negative** **سلبي****https://encrypted-tbn0.gstatic.com/images?q=tbn:ANd9GcT40wRNJCfqbJB46ycxq0gqvf4sgaxZcFAPVACGnnIAxa2gHxh_Tw** |
| What do you think about your experience with laughing gas?كيف كانت تجربتك مع الغاز الضَاحك؟  |  |  |  |
| Are you glad to have your tooth fixed /extracted?هل أنت سعيد بعد علاج/ خلع ضرسك؟ |  |  |  |
| How did we look after you when you had your treatment?كيف قمنا بالإعتناء بك خلال العلاج؟ |  |  |  |
| How friendly were we when you came to see us?ما مدى لطافتنا عندما قابلتنا؟  |  |  |  |
| How well did the dentist explain everything about treating your tooth?هل قام طبيب الأسنان بشرح واف عن طريقة علاج أسنانك؟  |  |  |  |
| Was it ok having your tooth fixed / extracted?هل كان علاج/ خلع أسنانك جيدا؟  |  |  |  |