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Summary

Background: Existing measures of children's dental anxiety have not been developed *with* children or based on a theoretical framework of dental anxiety.

Aim: To develop the Children's Experiences of Dental Anxiety Measure (CEDAM) and evaluate the measure's properties.

Design: The measure was developed from interviews with dentally anxious children. Children recruited from a dental hospital and secondary school completed the CEDAM and Modified Child Dental Anxiety Scale (MCDAS). A subgroup of children completed the CEDAM before and after receiving an intervention to reduce dental anxiety to examine the measure's responsiveness. Rasch and Classical test analyses were undertaken.

Results: Children were aged between 9 and 16 years (N=88 recruited from a dental hospital and N=159 recruited from a school). Rasch analysis confirmed the measure's uni-dimensionality. The CEDAM correlated well with the MCDAS (rho=0.67, p<0.01), had excellent internal consistency (Cronbach's alpha=0.88) and test-retest reliability (ICC=0.98). The CEDAM was also able to detect changes in dental anxiety following the intervention (baseline mean= 22.36, SD=2.57 and follow-up mean=18.88, SD=2.42, t(df=37)=9.54, p<0.01, Cohen's d=1.39).

Conclusions: The results support the reliability, validity and responsiveness of the CEDAM. Initial findings indicate it has potential for use in future intervention trials or in clinical practice to monitor children's dental anxiety.

Introduction

Dental anxiety affects a significant proportion of children, with over half of children in England reporting moderate dental anxiety and a further 10-14% reporting severe dental anxiety ¹. Children with dental anxiety are more likely to be infrequent or irregular users of dental services, have a higher prevalence of oral health problems and have worse oral health-related quality of life compared to children who do not experience dental anxiety ²⁻⁴. It is therefore important that these children are identified at an early stage so that their dental anxiety can be managed or reduced. However, a number of factors influence how the dentally anxious child presents at the dental clinic, making it sometimes difficult for clinicians to accurately detect dental anxiety through observation and clinician judgement alone ⁵. Indeed research has revealed that there is a weak relationship between dentists' and children's ratings of dental anxiety ⁶.

The use of self-report measures offers clinicians a reliable way of identifying children with dental anxiety. A variety of measures have been developed over the years, each with acknowledged strengths and limitations ⁷. The Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), the Modified Child Dental Anxiety Scale (MCDAS), Corah's Dental Anxiety Scale (DAS) and the Venham Picture Test (VPT) are all commonly used instruments but have differing psychometric properties. Clinicians and researchers therefore need to appraise which measure is most appropriate to their study aims and population. A recent systematic review revealed that the CFSS-DS had been employed most frequently in previous studies and had been used with a wide age range of children ⁷. However, as with several other scales, it had a limited focus and only measured the severity of fear in response to specific dental situations (e.g. hearing the dental drill, sitting in the dental chair). It was therefore proposed that, children who had not actually encountered these experiences may find it difficult to respond in terms of their hypothetical anxiety levels.

The Five Areas[™] cognitive behavioural assessment model of anxiety offers a holistic assessment approach which outlines how situational factors, unhelpful thoughts, unhelpful behaviours, physical symptoms and feelings are all important components of the anxiety experience, which can contribute to the maintenance of the condition ⁸. Assessing the factors which play a role in children's dental anxiety is a prerequisite for clinicians to understand how they can effectively manage or reduce the dental anxiety in their child patients ⁹. Therefore, it has been proposed that a measure which fails to assess all of the components of dental anxiety will only provide partial information about the individual's anxiety experience ¹⁰. Assessing the thought patterns, behaviours, physical symptoms and feelings experienced by children with anxiety can be extremely helpful for both dental practitioners and patients. This type of assessment enables practitioners to identify problem areas which may be maintaining the anxiety and could be the target of interventions (e.g. specific unhelpful thoughts or avoidance), and can also help inform and develop the patient's own understanding of why they are anxious ⁸.

In recent years a number of new measures, such as the Abeer Children Dental Anxiety Scale (ACDAS) ⁹ and the Index of Dental Anxiety and Fear (IDAF-4C) ¹¹, have been developed to assess the multidimensional components of dental anxiety and thus provide a more comprehensive assessment of dental anxiety. However, to date no measures of dental anxiety have been developed through undertaking research *with* children ¹²; and fully involving children in the development of the measure. Questionnaires that have not been developed from research with children may fail to assess the altered thoughts, behaviours, physical symptoms and feelings which are specific to children and may potentially use language which is not relevant or understandable to children ¹³. The need to actively involve children in research and to consider the developmental validity of child dental anxiety measures has therefore been highlighted ^{4, 12, 13}.

The aim of this study was to develop the Children's Experiences of Dental Anxiety Measure (CEDAM) *with* dentally anxious children, based on a cognitive behavioural assessment model of anxiety ⁸, which could assess aspects of dental anxiety which are important to children. This paper describes the development of the CEDAM and reports the findings from an evaluation study which examined its properties. The specific objectives of the evaluation study were to examine the performance of the measure's items (e.g. item fit and item response) and assess the internal consistency, test-retest reliability, construct validity and responsiveness of the measure. It is recognised that examining these properties is central to the evaluation of a patient reported outcome measure ¹⁴.

Materials and Method

Overview

The CEDAM was developed from data obtained from interviews with children with dental anxiety plus subsequent cognitive pre-testing and piloting of the measure. Throughout this paper, all participants under the age of 16 years will be referred to as 'children'. Previous focus groups revealed no preference for any one descriptor from the following: 'young people'; 'adolescents'; 'teenagers' or 'children'. Thus for simplicity, the use of the inclusive term 'children' was adopted.

Rasch analysis and classical test techniques were performed to examine the psychometric properties of the CEDAM with non-clinical and clinical populations. Ethical approval was granted from the University of Sheffield ethics committee and NRES Committee York and Humber: Leeds West REC (13/YH/0163) to undertake the research with the non-clinical and clinical participants respectively.

Stage 1. Development of the CEDAM

Theoretical model

The Five Areas[™] cognitive behavioural assessment model of anxiety was used as a framework to guide the interviews and measure development ⁸. The model outlines the components involved in the development and maintenance of anxiety, which include situational factors, unhelpful thoughts, unhelpful behaviours, physical symptoms and feelings, and highlights the interrelationships between these areas.

Participants

Children were involved at each stage of the study. To illustrate the number and sociodemographic profile of participants at different phases of the questionnaire development and testing, a flow chart has been provided (Figure 1).

Qualitative interviews

To identify the unhelpful thoughts, behaviours, physical symptoms and feelings which may be experienced by children with dental anxiety, in-depth interviews with dentally anxious children were undertaken until saturation was achieved. Thirteen children aged between 11-16 years participated in the qualitative interviews (three males and ten females) and interviews were transcribed and analysed using framework analysis ¹⁵. These data have been published elsewhere ¹⁶.

Item generation

The anxiety experiences reported by children with dental anxiety (see ¹⁶) were used to generate items which mapped on to four areas of the theoretical model (unhelpful thoughts, unhelpful behaviours, physical experiences and feelings). Situational aspects of dental anxiety were

not included within the measure because the focus of measure was to assess the *internal* components of dental anxiety experienced by children.

Cognitive pretesting and piloting

Cognitive pretesting was undertaken with children from a non-clinical population to increase the developmental validity of the measure. Interviews were undertaken until no further changes were suggested. Cognitive pretesting aims to assess the child's comprehension, judgement and response to each item included in the questionnaire and involves interviewing the child whilst he/she is completing the questionnaire ¹⁷. A total of 11 children (7 boys, 4 girls), aged between 8 and 15 years, participated in cognitive pretesting. Feedback about the content, language and response format of the CEDAM resulted in a substantial number of revisions being made to the measure. For example, children preferred response formats which were relevant to the specific items and domains rather than the Likert scales proposed.

The resultant measure was then examined by a team of experts (including health and clinical psychologists, a psychiatrist and a team of paediatric dentists) and a small number of additional changes were made. The measure was then piloted with children until no further revisions were suggested. A total of five children (3 boys, 2 girls) aged between 9 and 16 years, who were from a non-clinical population, piloted the measure.

Preliminary version of the CEDAM (prior to evaluation study)

Following this initial development the CEDAM contained 17 items. An example item and response format was: 'When I next visit the dentist I think I will...' 'not feel upset', 'feel a little upset', feel quite upset', feel very upset'. The 17-item version of the measure was tested within the evaluation study described below.

Stage 2. Evaluation study

Sample and procedure

The non-clinical sample was recruited from a large comprehensive secondary school in Berkshire, through a personal contact. Permission was granted from the head teacher of the school, written consent was gained from parents and assent from children. A sample of 159 children participated by completing both CEDAM and MCDAS measures (100% response rate) but two were excluded due to high levels of missing data. Due to the high prevalence of dental anxiety, school children were also asked a global anxiety question ('Overall when I go to the dentist...' 'I feel really scared' 'I feel quite scared' 'I feel a little scared and 'I don't feel scared at all') to identify children within this non-clinical sample who actually had dental anxiety (those children who identified some dental anxiety). Within the school sample, 68 (43%) children were male and 91 (57%) were female (mean age=12.60, SD=1.24). The Modified Child Dental Anxiety Scale (MCDAS) is a short, previously validated measure often seen as the current gold-standard for dental anxiety assessment, which contains eight items designed to assess dental anxiety in children. The measure has been used extensively within the field and asks children to rate how anxious they feel in response to a variety of dental situations or experiences (1= not worried/relaxed, 5=very worried). Total scores can range from 8 to 40, with higher scores reflecting higher levels of dental anxiety.

The clinical sample was obtained from a paediatric dental clinic within a UK based dental hospital. All new patients aged between 9 and 16 years old who had been referred to the dental clinic were asked to respond to a question on a screening slip which was offered to them at their first appointment ('please tell us how you feel about going to the dentist'). Those that responded they were 'a little bit worried' or 'very worried' were invited to take part in the study. Written consent was obtained from parents and assent from children. A sample of 88 anxious children from a clinical population participated in the study, 32 (36%) children were male and 56 (64%) were female (mean age=12.64, SD=1.81). The majority of these children were recruited for the specific purposes of this study (N=50, response rate= 100%). However, 38 were dentally anxious children (aged between 9-16 years old) who were already participating in an ongoing research study being undertaken in a UK based dental hospital and two UK based community dental services. The research aimed to evaluate the feasibility and preliminary effectiveness of a Cognitive Behaviour Therapy (CBT)-based guided self-help intervention designed to reduce dental anxiety. Details of how this sample were recruited to the research and the how the CBT intervention was developed and delivered have been published elsewhere ¹⁸).

Therefore a total of 247 children aged between 9 and 16 years (mean age=12.62, SD=1.47) participated in the baseline evaluation study, the majority of whom were female (N=147, 60%).

Follow-up CEDAM data (required to evaluate the responsiveness of the measure) were available for the 38 children who had received the CBT-based guided self-help intervention as part of a larger research project ¹⁸. These children had already completed the CEDAM at baseline and following their engagement with a CBT-based intervention. Children completed repeat CEDAM questionnaires following their attendance at three dental appointments where they had received a new CBT-based guided self-help from their dental team (www.llttf.com/dental). Of this group, 28 (73.7%) children were female and the mean age was 12.63 years (SD=1.61).

Rasch analysis

The fit and function of the 17-item measure were examined using a Rasch item response theory model. Rasch analysis was originally used in educational testing, but more recently has been used in the development and evaluation of patient-reported outcome measures ¹⁹⁻²¹. Formal testing of a scale against a mathematical model assesses how well the participants' responses fit the model ²². According to this method, the items chosen for the final measure should be unidimensional (i.e. the questions should all measure the same construct), be free from differential item functioning (DIF), i.e. they function in the same way across groups, and fit the model expectations ²³. The overall score can then be expressed in logits (log odds probability units), thus converting the ordinal raw scores to an interval scale from which accurate change scores can be calculated. The measure was tested with the unrestricted or partial credit model, using the method suggested by Tennant and Conaghan ²³ involving:

- Category discrimination: this analyses response patterns to assess whether participants are able to discriminate between the different response options. Where these are disordered, adjacent categories can be collapsed to reduce the number of response options.
- 2. Differential item functioning (DIF) was analysed by age (9-12 years and 13-16 years) and gender.
- 3. Item fit to the model: if the data fit the Rasch model, each item and person fit residual should be within the range +/- 2.5 and the mean item and person fit statistics should be close to zero with a standard deviation of one ²⁴. Finally, the individual items and summary chi-square interaction statistics should be non-significant (> 0.05), although these are subject to Bonferroni adjustment based on the number of items.

Once a unidimensional scale had been achieved, a transformation from raw score to interval data was undertaken. The Rasch analysis was undertaken using RUMM2030 software (RUMM Laboratory Pty, Ltd, WA, Australia). All further analyses were based on the scale created from this analysis. Subsequent classical test analysis was also undertaken on this revised version of the CEDAM.

Classical test analysis

Reliability

Internal consistency examines the extent to which all of the items in the measure assess the same underlying concept. The internal consistency of the CEDAM was assessed using the Cronbach's alpha test. To examine whether scores are consistent over time (scores are stable when no real change is likely to have occurred) test–retest reliability should be examined by asking individuals to complete the measure on more than one occasion ²⁵. To assess the test-retest reliability of the CEDAM, 14 children (mean age=13.36, SD=0.50) from the non-clinical population completed the measures again two weeks after they had initially completed the baseline measure. Codes were used to link baseline and test-retest data and intra-class correlations were calculated for baseline and retest scores.

Validity

The construct validity of the CEDAM was examined by undertaking 'known group' analysis and comparing the anxiety scores between the clinical and non-clinical groups of children. It was expected that children from the clinical sample, who had indicated they were dentally anxious, would score higher on the CEDAM than children from the school sample. Tests of differences were employed to examine the differences in dental anxiety scores between these two groups.

Concurrent validity is a type of criterion validity and can be demonstrated by comparing the results of the measure to an existing 'gold standard' test, which aims to assess the same construct ²⁵. In order to examine the concurrent validity of the CEDAM all participants were asked to complete the MCDAS ²⁶ at the same time. Correlational analysis was employed to examine the relationship between the CEDAM and MCDAS scores within the current study.

Responsiveness to change

The measure's ability to detect change in anxiety levels pre and post the CBT-based intervention was evaluated to provide preliminary evidence of the measure's ability to detect change in dental anxiety, when change is expected. Related t-tests were performed on pre-post intervention CEDAM and MCDAS scores.

Results

Rasch analysis

Given that the CEDAM was primarily designed for use as a clinical assessment tool the analysis was performed using data from the clinical sample (n=88). The initial scale showed significant misfit to the model. Four items had disordered thresholds indicating that the response

categories were not functioning as expected. Feedback from children completing the measures had also revealed some children experienced difficulties in differentiating between specific responses (e.g. differentiating between feeling 'quite upset' and 'a little upset'). Therefore, in line with participant feedback and in order to maintain a consistent response format, the 4-point scale was changed to a 3-point scale by collapsing appropriate adjacent categories. For example, in response to the question 'When I next visit the dentist I think I will...' the three point scale created was: 'Feel very upset,' 'Feel a little upset' and 'Not feel upset', (which combined the 'Feel quite upset' and 'Feel a little upset' responses). No differential item functioning was identified by age group or gender (i.e the items had a similar function across groups). Three items were removed (items relating to nervousness, wanting to walk out during appointments and confidence that the dentist would explain things to them) based on their fit statistics and feedback from participants. The resultant 14item scale demonstrated uni-dimensionality.

Overall fit statistics at each stage of analysis are shown in Table 1, along with the ideal fit statistics to the Rasch model. Appendix 1 shows the person-item threshold map which indicates that participants are distributed in a similar pattern to the items and that the items measure the impacts of dental anxiety along the construct from least to most dentally anxious. As the items fit the Rasch model, a transformation from the raw score to interval scaling is shown in Table 2. This conversion allows the raw ordinal score to be converted to an interval score allowing accurate calculation of change scores. All further analyses were based on the 14-item scale created from this analysis (see Appendix 2).

Dental anxiety scores

Mean scores for the 14-item CEDAM and 8-item MCDAS according to age, gender and sample type can be seen in Table 3. Baseline MCDAS scores were normally distributed in clinical and non-clinical samples. Baseline CEDAM scores had high levels of kurtosis within the non-clinical sample (Skewness =1.40 (SE=0.19), Kurtosis =7.00 (SE=0.38), N=158), however, Skewness and Kurtosis values for CEDAM scores were within the acceptable range (<u>+</u>2) within the clinical sample (Skewness=0.37 (SE=0.26), Kurtosis=1.52 (SE=0.52), N=85) ²⁷.

An independent t-test revealed females had higher MCDAS scores than their male counterparts (t=-3.56 (df=237) = p<0.01) and Mann-Whitney analysis revealed no significant difference between females and males in their CEDAM scores (Z=-0.14, p=0.89, N=243).

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Correlational analysis revealed no association between age and dental anxiety, as measured by both the CEDAM (rho=-0.10, p = 0.55, N=243) and MCDAS (r=0.07, p=0.32, N=239).

Classical test analysis

This analysis was undertaken on data obtained from both the clinical and non-clinical samples (either collectively or independently, as appropriate) and a summary of this analysis can be found in Table 4.

Internal consistency

Cronbach's coefficient alpha scores were computed for the CEDAM and MCDAS and demonstrated adequate internal consistency for both measures (0.88 and 0.84, respectively).

Test-retest reliability

Intra-class correlation coefficients revealed that with a retest period of two weeks the testretest reliability of the CEDAM and MCDAS was excellent (0.98 and 1.0, respectively).

Construct and concurrent validity

To assess the 'Known groups' validity of the CEDAM, the scores of the clinical sample (which consisted of children who had reported being dentally anxious) and non-clinical school sample who had not reported dental anxiety were compared. This examined whether the CEDAM could produce an 'anxiety score' which could be used to differentiate children with and without dental anxiety.

Mann-Whitney and independent t-tests revealed significant differences in anxiety scores between the two groups, with children from the clinical sample scoring higher on the CEDAM (Z=-6.82, p<0.01, N=168) and MCDAS (t=-5.14, df=163, p<0.01) than children from the general population (school) sample who reported they did not suffer from dental anxiety (e.g. those children who responded 'I don't feel scared at all' to the global dental anxiety item 'Overall, when I go to the dentist....'). Correlation coefficients revealed a moderate/high inter-correlation between the CEDAM and MCDAS (rho= 0.67, N=235, p<0.01), indicating a significant positive relationship between the two measures.

Responsiveness to change

Related t-tests revealed that both the MCDAS (pre-intervention mean=22.36 (SD=6.72), post-intervention mean=17.41 (SD=5.89), t=8.27, df=33, p<0.01, Cohen's d=1.27) and CEDAM (pre-

intervention mean=22.36 (SD=2.57), post-intervention mean=18.88 (SD=2.42), t=9.54, df=37, p<0.01, Cohen's d=1.39) were able to detect changes to dental anxiety following the CBT-based intervention.

Discussion

The CEDAM is a self-report measure of children's experience of dental anxiety which assesses the unhelpful thoughts, behaviours, physical symptoms and feelings experienced by children. The measure was designed to be used as a patient reported outcome measure of dental anxiety and was based on an established cognitive behavioural clinical assessment model ⁸, with the aim of increasing the measure's clinical application and relevance by assessing change in key domains that alter during times of anxiety.

The psychometric properties of the 14 item CEDAM were comparable with the MCDAS for children aged 9-16 years and demonstrated excellent internal consistency and test-retest reliability. Any potential concerns about the validity of CEDAM for such a wide age range of children were therefore unfounded. Indeed, many other existing dental anxiety measures have also been developed for use with a wide age range of children ⁷. It was, however, interesting to note that girls reported significantly higher levels of anxiety using the MCDAS than was the case for CEDAM (which did not identify a significant difference according to gender). It may be that because CEDAM offers a more comprehensive assessment of how dental anxiety impacts on children (in terms of unhelpful thoughts, feelings and behaviours) the measure was able to detect that worries and concerns of boys and girls are largely similar. Differences in prevalence rates between boys and girls could be the result of a gender response bias with males feeling less able to report high levels of anxiety. Further qualitative work would seem to be warranted, therefore, to determine whether CEDAM has addressed this potential gender response bias, or whether it is failing to capture gender differences in dental anxiety levels.

The measure was positively correlated with the MCDAS ²⁶ and was also able to identify differences in anxiety between a clinical population, who self-identified as being dentally anxious, and a nonclinical sample of children who did not report dental anxiety. One of the main advantages of the CEDAM, over other available measures of children's dental anxiety, is that the CEDAM was developed with children who were experiencing dental anxiety and therefore it assesses experiences that this group specifically identify as central to their anxiety and uses an accessible language and concepts appropriate for this age group. It is paramount that patient-reported outcome measures reflect the outcomes deemed important by the patient group and thus are developed with active engagement by the target population ^{17, 28}. Within the current study, a series of qualitative interviews/focus groups were undertaken with children and cognitive pretesting/piloting of the measure was also conducted to ensure this measure of dental anxiety was child-centred. However, it is worth noting that the questionnaire did not seek to explore children's concerns about specific items of treatment, such as oral injections. Whilst it is recognised that some dentally anxious children may have a needle phobia, the purpose of this new measure is to capture more generic experiences of dental anxiety. One item does, however, ask children to rate how worried they are that the dentist will do something that will hurt. Thus a child who anticipates that an injection will be very painful, will have the opportunity to respond accordingly.

The CBT-based assessment framework, which guided the development of the CEDAM, ensured that the resultant measure would have application as a clinical assessment tool. The CBT literature also suggests that children as young as 7-years have the cognitive ability to relate to the underlying concepts. Children's responses to the items included in the measure could be used to help the patient, carers and dental team understand the factors which could be maintaining the dental anxiety, whilst at the same time highlighting priority areas for intervention. For example, if unhelpful cognitions are identified (e.g. 'I think if I asked the dentist to stop what they were doing they would not stop') then the dental practitioner can address these with the patient (e.g. agree a stop signal) in order to modify unhelpful thoughts and thereby reduce the child's dental anxiety⁴.

The results of this study provide support for the reliability and validity of this new measure, however, patient reported outcome measures need to be both reliable and responsive to change ^{29,} ³⁰. The CEDAM has been designed in a way which promotes the measure's responsiveness (e.g. it assesses children's current anxieties and does not ask children to recall how anxious they felt in response to previous experiences). This promotes the responsiveness of the measure to detect short-term changes in dental anxiety, which is important if a measure is to be used to evaluate changes in patient symptoms or experiences over time. The CEDAM was able to detect reductions in children's dental anxiety following the implementation of a CBT-based intervention that had been designed to reduce dental anxiety levels. The Rasch analysis undertaken also generated an algorithm which can be used to convert raw ordinal scores to interval level scores which can be used to more accurately calculate change. This is related to the fact that ordinal scales are nonlinear, resulting in a sigmoid curve when the raw scores are plotted. Thus the values at the margins of the curve cover a

wider part of the underlying trait than those at the centre. Conversion to a linear scale eliminates this discrepancy, allowing change to be measured accurately regardless of where the score lies along the curve.

An acknowledged limitation of the current research is that the analysis of the measure's responsiveness to change was undertaken on data obtained from a relatively small sample (N=38). Further work is needed to identify the minimally clinical important difference (MCID) in the reduction of dental anxiety when using this measure before it can be recommended for widespread use as a patient-reported outcome measure to determine the effectiveness of any interventions. It has been recommended that a mixture of patient-based and clinical-based anchors should be employed to reliably establish a measure's MCID^{29, 30}.

The rationale for the CEDAM was to design a measure to provide insight into what is maintaining the child's anxiety and to measure change in that anxiety in response to an intervention. Its value as a potential screening tool, however, remains undetermined. Clearly, any anxiety measure which has thresholds or cut off scores for low or high anxiety levels could have important applications in the commissioning and provision of children's dental services. A child found to have clinically significant anxiety levels may benefit from referral to specialist services, which are better equipped to manage the child's dental anxiety with appropriate psycho-educational or pharmacological approaches.

It should also be noted that in the present study a comparison between MCDAS and CEDAM was only undertaken as part of the evaluative process for CEDAM reliability, as MCDAS offers a similar age range (8-15 years) for respondents. There was no intention to suggest one instrument was superior to another, as they each have merit in different clinical or research contexts.

Future work is now needed to investigate the usefulness and feasibility of utilising the CEDAM as a clinical assessment tool with the potential to help clinicians, children and carers understand and target specific factors that are contributing to the child's dental anxiety. Whilst the burden presented to the child, in completing CEDAM, is minimal (taking around 5 minutes), busy clinical practices may lack the resources or incentives to administer and analyse the instrument. A study is currently underway to determine the acceptability of an electronic version of CEDAM which may address some of the anticipated barriers to its routine use. Furthermore, primary care dentists will need to be persuaded of the evidence base and benefits of pre-treatment anxiety assessments for their young patients. At a more fundamental level, the need for effective communication between

child, parent/carer and dental professional is paramount in the holistic diagnosis and management of dental anxiety^{31, 32}.

Conclusion

The findings of the study revealed that the CEDAM is a reliable and valid measure of dental anxiety in children aged 9-16 years. This is the first measure of dental anxiety developed from inclusive research with dentally anxious children and based on a clinical assessment model of anxiety.

Why this paper is important to paediatric dentists

- Measures of children's dental anxiety need to assess the concerns and experiences of children. Through undertaking research with children the CEDAM has been developed to provide clinicians with a valid and reliable child-centred measure of dental anxiety.
- The CEDAM is a clinical assessment tool which can help clinician's understand their patient's dental anxiety and the factors which may be maintaining that anxiety. This information is critical for the development of appropriate treatment plans for children who have dental anxiety. CEDAM is available on request from

https://www.sheffield.ac.uk/dentalschool/research/create/cedam.

• The CEDAM could be used to monitor children's dental anxiety, and changes in dental anxiety, that occur over time or following clinical or psychological interventions.

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Disclosure statement

Chris Williams is the author of a range of CBT-based resources that address anxiety, depression and other mental health problems. These are available commercially as books, cCBT products, and classes. He receives royalties, and is a shareholder and director of a company that commercialises these resources. The other authors have declared no other competing interests.

Author's contributions

All authors were involved in the conception of the idea and the development of the measure. A.M. and E.G. collected the data. E.G, A.M., F.G and J. P. analysed the data. J.P and H.R led the writing and all authors contributed to manuscript revision.

References

1. Holmes R, Porter J, Vernazza C, Tsakos G, Ryan R, Dennes M. Children's Dental Health Survey 2013. Country Specific Report: England. London: Health and Social Care Information Centre 2015.

2. Rantavuori K, Lahti S, Hausen H, Seppa L, Karkkainen S. Dental fear and oral health and family characteristics of Finnish children. Acta Odontol Scand 2004; 62: 207-13.

3. Luoto A, Lahti S, Nevanpera T, Tolvanen M, Locker D. Oral-health-related quality of life among children with and without dental fear. Int J Paediatr Dent 2009; 19: 115-20.

4. Carrillo-diaz M, Crego A, Armfield J, Romero M. The moderting role of dental expectancies on the relationship between cognitve vulnerbility and dental fear in children and adolescents. Community Dent Oral Epidemiol 2013; 41: 269-78.

5. ten Berge M, Veerkamp JSJ, Hoogstraten J, Prins PJM. Childhood dentl fear in the Netherlands: prevlence and normative data. Community Dent Oral Epidemiol 2002; 30: 101-7.

6. Barros L, Buchanan H. Correspondence between dentist and child ratings of dental anxiety in Portugal: A preliminary study. Rev Port Estomatol Med Dent Cir Maxilofac 2011; 52: 13-5.

7. Porritt J, Buchanan H, Hall M, Gilchrist F, Marshman Z. Assessing children's dental anxiety: a systematic review of current measures. Community Dent Oral Epidemiol 2013; 41: 130-42.

8. Williams C, Garland A. A cognitive-behavioural therapy assessment model for use in everyday clinical practice. Adv Psychiatr Treat 2002; 8: 172-9.

9. Al-Namankany A, Ashley P, Petrie A. The Development of Dental Anxiety Scale with Cognitive Component for Children and Adolescents. Pediatr Dentist 2012; 34: 219-24.

10. Armfield JM. How do we measure dental fear and what are we measuring anyway? Oral health Prev Dent 2010; 8: 107-15.

11. Armfield JM. Development and Psychometric Evaluation of the Index of Dental Anxiety and Fear (IDAF-4C). Psychol Assess 2010; 22279-287.

12. Marshman Z, Gibson BJ, Owens J, Rodd HD, Mazey H, Baker SR, et al. Seen but not heard. A systematic review of the place of the child in 21st century dental research. Int J Paediatr Dent 2007; 17: 320-7.

13. Porritt JM, Buchanan H, Hall M, Gilchrist F, Marshman Z. Assessing children's dental anxiety: a systematic review of current measures. Community Dent Oral Epidemiol 2013; 41: 130-42.

14. Guyatt GH, Bombardier C, Tugwell PX. Measuring disease-specific quality of life in clinical trials. CMAJ 1986; 134: 889-95.

15. Ritchie J, Spencer L, editors. Qualitative data analysis for applied policy research. London: Routledge; 1994.

16. Morgan AG, Rodd HD, Porritt JM, Baker SR, Creswell C, Newton T, et al. Children's experiences of dental anxiety. Int J Paediatr Dent 2016; 27: 87-97.

17. Woolley ME, Bowen GL, Bowen NK. Cognitive Pretesting and the Developmental Validity of Child Self-Report Instruments: Theory and Applications. Res Soc Work Pract 2004; 14: 191-200.

18. Porritt J, Rodd H, Morgan A, Williams C, Gupta E, Kirby J, et al. Development and Testing of a Cognitive Behavioral Therapy Resource for Childrens Dental Anxiety. JDR Clinical & Translational Research 2017; 87-97.

19. Batcho CS, Tennant A, Thonnard JL. ACTIVLIM-Stroke: a crosscultural Rasch-built scale of activity limitations in patients with stroke. Stroke 2012; 43: 815-23.

20. Chien CW, Rodger S, Copley J. Development and Psychometric Evaluation of a New Measure for Children's Participation in Hand-Use Life Situations. Arch Phys Medic Rehabil 2014; 96: 1045-55

21. Shelton AT, Houghton NY, Morris DO, Latchford GL, Bekker HL, Munyombwe T. The development and validation of a psychological questionnaire for patients undergoing orthognathic treatment. Orthod Craniofac Res 2015; 18: 51-64.

22. Rasch GW. Probabilistic models for some intelligence and attainment tests. Copenhagen: Danish Institute for Education Research 1960.

23. Tennant A, Conaghan PG. The Rasch measurement model in rheumatology: what is it and why use it? When should it be applied, and what should one look for in a Rasch paper? Arthritis Rheum 2007; 57: 1358-62.

24. Kersten P, White PJ, Tennant A. Is the pain visual analogue scale linear and responsive to change? An exploration using Rasch analysis. PLoS One 2014; 9: e99485.

25. Roach KE. Measurement of Health Outcomes: Reliability, Validity and Responsiveness. JPO 2006; 18: 8-12.

26. Wong HM, Humphris GM, Lee GTR. Preliminary validation and reliability of the modified child dental anxiety scale. Psychol Rep 1998; 83: 1179-86.

27. Tabachnick B, Fidell L. Using Multivariate Statistics. 6th ed. Essex: Pearson Education Limited; 2013.

28. Marshman Z, Gupta E, Baker SR, Robinson PG, Owens J, Rodd HD. Seen and heard: towards child participation in dental research. Int J Paediatr Dent 2015; 25.

29. Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. J Chronic Dis 1987; 40: 171-8.

30. Revicki D, Hays RD, Cella D, Sloan J. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. J Clin Epidemiol 2008; 61: 102-9.

31. Jaakkola S, Lahti S, Raiha H, Saarinen M, Tolvanen M, Aromaa M, et al. Dental fear affects adolescent perception of interaction with dental staff. Eur J Oral Sci 2014; 122: 339-45.

32. Zhou Y, Cameron E, Forbes G, Humphris G. Systematic review of the effect of dental staff behaviour on child dental patient anxiety and behaviour. Patient Educ Couns 2011; 85: 4-13.

Table 1. Fit of the CEDAM to the Rasch model

Analysis name	Item residual		Person residual		Chi-square		Reliability
	Mean	SD	Mean	SD	Value (df)	Р	
Initial analysis	-0.01	-1.27	-0.19	1.13	51(34)	0.034	0.91
Rescore to 3 categories	-0.20	0.70	-0.27	0.92	28 (28)	0.271	0.86
Remove items "walking out", "explaining" and "nervous"	-0.21	0.74	-0.28	0.99	34 (34)	0.447	0.88
Ideal	0	1	0	1		>0.004*	>0.7

* Bonferroni adjustment for 14 items; SD=standard deviation; df=degrees of freedom

 Table 2. Conversion from raw score to interval level score.

Raw score	Interval score	Raw score	Interval score
14	14.00	29	25.34
15	15.97	30	25.78
16	17.43	31	26.23
17	18.49	32	26.69
18	19.36	33	27.17
19	20.12	34	27.69
20	20.80	35	28.25
21	21.42	36	28.89
22	21.99	37	29.68
23	22.53	38	30.78
24	23.04	39	33.18
25	23.52	40	39.53
26	23.99	41	41.43
27	24.44	42	42.00
28	24.89		

Table 3. Dental anxiety scores by participant group/demographics

Participant group	Baseline CEDAM mean (SD)	Baseline CEDAM range	Baseline MCDAS mean (SD)	Baseline MCDAS range
Clinical sample	21.97 (SD=3.01) N=85	14-42	24.05 (SD=6.64) N=82	8-38
Non-clinical sample				
no dental anxiety reported	18.80 (SD=2.97) N=83	14-33.18	15.86 (SD=5.76) N=83	8-31
dental anxiety reported	22.73 (SD=2.25) N=73	15.97-42	22.88 (SD=6.70) N=73	8-38
9 year olds	19.96 (SD=2.07) N=2	18.49-21.42	24.50 (SD=12.02) N=2	16-33
10 year olds	21.70 (SD-3.22) N=10	17.43-27.69	22.20 (SD=6.81) N=10	13-36
11 year olds	21.33 (SD=2.83) N=47	14-26.23	20.76 (SD=7.40) N=46	8-34
12 year olds	20.94 (SD=3.73) N=64	14-33.18	19.83 (SD=7.10) N=63	8-36
13 year olds	20.83 (SD=2.67) N=47	14-25.78	20.49 (SD=8.49) N=47	8-38
14 year olds	20.90 (SD=4.32) N=45	14-42	20.63 (SD=6.44) N=46	8-35
15 year olds	21.08 (SD=3.50) N=24	14-28.25	23.36 (SD=6.06) N=22	8-31
16 year olds	24.83 (SD=6.11) N=4	18.49-33.18	27.33 (SD=11.37) N=3	18-40
Males	20.93 (SD=3.46) N=98	14-33.18	18.86 (SD=7.15) N=98	8-35
Females	21.19 (SD=3.53) N=145	14-42	22.23 (SD=7.13) N=141	8-40
Total Sample	21.09 (SD=3.50) N=243	14-42	20.85 (SD=7.32) N=239	8-40

Measure	Internal consistency (Cronbach's alpha)	Test-rest reliability at two weeks*	'Known-groups' validity**	Concurrent validity***	Number of participants with missing responses at baseline
14-item CEDAM	0.88 (N=243)	ICC=0.98 (N=14)	Non-anxious school group: Mean=18.80 (SD=2.97), N=83 Clinical group: Mean=21.97 (SD=3.01), N=85 (Z=-6.82, p<0.01)	rho=0.67 (N=235)	N=4
8-item MCDAS	0.84 (N=239)	ICC=1.0 (N=14)	Non-anxious school group: Mean=15.90 (SD=5.76), N=83 Clinical group: Mean=24.05 (SD=6.64), N=82 (t=-8.47, <i>df</i> =163, p<0.01)		N=8

Table 4. Summary of reliability and validity estimates

*Non-clinical sub-sample

**Difference between anxiety scores of children from clinical sample and children from the school sample who did not identify as having dental anxiety

*** Correlation coefficient between MCDAS and CEDAM