Does the Use of a Self-help Cognitive Behavioural Therapy Intervention Reduce Dental Anxiety in Children?

Susan Welford

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

Supervisors

Professor Zoe Marshman[1], BDS, MPH, DDPH, FDS (DPH), PhD

Professor Peter Day[2], PhD, FDS (Paeds) RCS (Eng), FRCD (Canada), PGCLTHE, BDS, MFDS RCS (Eng), M Dent Sci, M Paed Dent RCS (Eng)

Professor Bernadette Drummond[2], BDS, MSc, PhD, FRACDS, FDSRCS Honorous Causum

Dr Rachael Nichol[3], BChD, MFDS RCS (Eng), MDent Sci (Paed Dent), MPaed Dent RCS (Eng), FDSRCS (Paed Dent) (Eng), PG Cert HCL, PG Cert Clin Ed, FHEA

1. School of Clinical Dentistry, University of Sheffield, Claremont Crescent, Sheffield, S10 2TA
2. Department of Paediatric Dentistry, School of Dentistry, University of Leeds, LS2 9LU, Bradford District Care Trust Salaried Dental Service and Leeds Dental Institute
3. Mid Yorkshire NHS Hospitals Trust Community Dental Services, Newstead House, 11 Bond St, Wakefield WF1 2QP

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Abstract

Background

Dental anxiety is a common reason for referral to Community Dental Services. Previous studies have shown a positive impact of self-help cognitive behavioural therapy (CBT) in reducing dental anxiety.

Aim

To investigate the effects of a self-help CBT intervention on dental anxiety and health-related quality of life (HRQoL) for dentally anxious children aged 8-16 years referred to a Community Dental Service.

Method

Children aged 8-16 years with dental anxiety received a self-help CBT intervention during dental treatment. Dental anxiety and HRQoL were assessed using the "Children's Experiences of Dental Anxiety Measure" and "Child Health Utility 9D" questionnaires before and after dental treatment, and three months later.

Results

In total, 41 participants were recruited (mean age 11.0 years), while 28 and 15 completed the first and second follow-up questionnaires respectively. The mean reduction of 3.2 in dental anxiety was statistically significant ($p=0.001$). The reduction was maintained three months after treatment. Over three-quarters of participants (77.0%) reported feeling less worried after the intervention. A statistically significant improvement in HRQoL was identified ($p=0.023$).

Barriers to recruitment and retention included patients declining to participate, eligibility, and not being brought to appointments.

Conclusion

A self-help CBT intervention led to reduced dental anxiety and improved HRQoL among children in the community dental service. Findings support the use of self-help CBT for dentally anxious children in similar services. A randomised controlled trial is recommended to compare the intervention to standard behaviour management techniques. Recruitment challenges should be accounted for in future research with this population.

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Abbreviations

ADHD	Attention deficit hyperactivity disorder
ANOVA	Analysis of Variance
AR	Applied relaxation
ASA	American Society of Anesthesiologists
BAT	Behavioural Avoidance Test
BMP	Behaviour management problems
CBT	Cognitive behavioural therapy
C-CBT	Computerised cognitive behavioural therapy
CDHS	Child Dental Health Survey
CDS	Community dental services
CEDAM	Children's Experiences of Dental Anxiety Measure
CFSS-DS	The children's fear survey schedule dental subscale
CHU9D	Child Health Utility 9D
DAS	Dental anxiety scale
DFA	Dental Fear and anxiety
DFS	Dental Fear Survey
DFSS-SF	Dental fear schedule subscale short form
dmft	Decayed, missing and filled primary teeth
DMFT	Decayed, missing and filled permanent teeth
FIS	Facial image scale
GA	General anaesthesia
GDP	General dental practitioner

HRQoL	Health-related quality of life
IHS	Inhalational sedation
IRAS	Integrated Research Application System
IV	Intravenous
LA	Local anaesthesia
MCDAS	Modified child dental anxiety scale
MDAS	Modified dental anxiety scale
MID	Minimally important difference
NDAMS	Nurse-led dental anxiety management service
NHS	National Health Service
NIHR	National Institute for Health and Care Research
NO	Nitrous oxide
OHRQoL	Oral health-related quality of life
RA	Relative analgesia
REC	Research ethics committee
SAAD	Society for the Advancement of Anaesthesia in Dentistry
S-DAI	Short version of dental anxiety inventory
SFP	Smiley Faces Programme
STROBE	Strengthening the reporting of observational studies in epidemiology
VCAS	Venham Clinical Anxiety Scale
VCCS	Venham Clinical Cooperation Scale
VPS	Venham Picture Scale
WNB	Was not brought

Chapter 1 Background and Literature Review

1.1 Introduction

The World Health Organisation states that good oral health "is integral to general health and supports individuals in participating in society and achieving their potential" [1]. Maintenance of good oral health is therefore essential for children. Within the United Kingdom (UK), many children suffer from poor oral health, with dental caries being the most prevalent preventable condition within the UK child population [2]. Due to this high level of need, it is essential that children can access and accept dental treatment. A significant barrier to children accepting dental treatment is that of dental fear and anxiety (DFA).

This literature review aims to define DFA, outline its prevalence and the impact it can have on children, their families, and the wider health system. Current methods of managing DFA are discussed along with the evidence base with a focus on cognitive behavioural therapy. This provides the rationale for this study on the use of a self-help cognitive behavioural therapy resource service-wide within a Community Dental Service (CDS) to manage children with DFA.

1.2 Definitions of dental fear, dental anxiety and dental phobia

Some dental anxiety may be expected prior to, and during a child's attendance for dental care. Anticipation of a negative stimulus may trigger the "fight or flight" response. This response by the autonomic nervous system releases adrenaline, causing physiological changes such as increased blood flow to muscles and increased heart rate. These may feel unpleasant and distressing to a child. When the level of anxiety or fear is disproportionate to the threat this can have negative effect on the child's ability to receive care, and in turn impact upon their quality of life. Due to these differing levels of anxiety, on a scale from expected through to disproportionate, it is important to define each term.

- Dental Fear

Dental fear has been described by Klingberg et al as "a normal emotional reaction to a specific external threatening stimulus in the dental situation" [3]. For example, this may be

fear of a stimulus such as the dental drill or injection and may be considered as a natural response to the stimulus.

- Dental Anxiety

Klingberg et al defined dental anxiety as apprehension that something dreadful is going to happen in relation to dental treatment, in combination with the feeling of losing control [3]. Whilst fear has been defined as a reaction to immediate danger or a sequela of encountering a feared stimulus, anxiety can be defined as a reaction to potential, or anticipated stimulus/danger [4]. Whereas dental fear is response to a specific stimulus such as on seeing the dental drill, dental anxiety may be a general apprehension occurring prior to the dental visit, anticipation of feared stimulus. Anxiety also triggers the autonomic nervous system and may involve worry, hypervigilance, and cognitive distortions [5].

- Dental phobia

Dental phobia may be defined as severe form of dental anxiety [3]. It involves excessive, persistent anxiety which may relate to a specific stimulus (e.g. injection) or to the whole dental setting. It may involve disproportionate levels of anxiety lasting over 6 months; avoidance of dental visits, or experience of intense dental fear during treatment, out-of-proportion to the stimulus or situation; and significant distress or functional impairment [6].

As dental fear, anxiety and phobia may be considered the same emotional response at varying points of a scale, or on a continuum, the term dental fear and anxiety (DFA) is commonly used in the literature and will be used from here.

1.3 Dental behaviour management problems and the relationship with dental fear and anxiety

Klingberg et al define behaviour management problems (BMP) as “severe disruptive behaviours resulting in delay in treatment, or rendering the treatment impossible” [7].

Prevalence of dental BMP was assessed by Klingberg at al 1994 [7]. This retrospective population study assessed records of 4505 Swedish children aged 4-11 years and found 10.5% children demonstrated BMP, with this more common in younger children: 16% of 4–6-year-olds vs. 6% of 9–11-year-olds. Missed appointments were more common in those exhibiting BMP; 28% vs. 15%. Children with BMP were more likely to have restorative

treatment without LA; 33% compared to 22%. These children also had more carious surfaces (4,70 vs. 1.58) fewer restored surfaces (1.82 vs, 2.33) than children without BMP. The retrospective nature of this study means levels of BMP may be underestimated, as dental notes may have not accurately recorded all BMP. BMP at lower levels than the study's strict cut off would not have been recorded. In addition, there was variation between dentists in the methods of behaviour management used and the comprehensiveness of dental records.

The relationship between DFA and BMP is not always clear clinically. As described by Öst et al, children's response to DFA can vary significantly from quiet, avoidance behaviour, to uncooperative, disruptive behaviour [8]. A Swedish population study by Klingberg at al, assessed 3,204 urban Swedish children aged 4 to 6 and 9 to 11 years [9]. This identified that children with BMP in their records scored higher for dental anxiety than children without BMPs. BMP was more common in those with highest levels of DFA than those with lower scores. However, this study also has the limitations of a retrospective study relying of dental records and may underestimate BMP.

The relationship between DFA and BMP varies across populations, age groups, maturity, cognitive properties [8]. It can also be affected by previous dental experiences. Research in this field commonly does not distinguish between DFA and BMP. Research often measures change in BMP as a surrogate end point, whereas this may not directly correlate to change in DFA.

In summary, these studies suggest that BMP are associated with higher levels of DFA. Also, those with BMP are more likely to have treatment without LA, to miss appointments, and to be left with unrestored teeth than those without BMP. However, due to limitations of the studies, it is important to assess each child on an individual basis, as an absence of BMP does not always indicate low levels of DFA.

1.4 Aetiology of dental anxiety in children

Development of fear and anxiety can be a normal part of childhood with prevalence and severity of fear decreasing with age into adulthood [10]. However, this normal developmental fear and anxiety can be differentiated from clinical fears and phobias in several ways: whether the fear is age- or stage-specific, how long it persists, and whether it interferes with functioning [11]. For DFA this may mean avoidance of dental appointments, or exhibiting

challenging behaviour. The aetiology of this DFA is considered multifactorial [12]. Various factors have been described in the literature. Beaton et al split these factors into exogenous and endogenous sources [13]. Exogenous factors are external contributory factors. These include direct learning from traumatic experiences and vicarious learning through significant others and the media. Endogenous factors are internal contributory factors which make an individual more likely to develop dental anxiety. This can include inheritance and personality traits.

It is important to consider that much of the research around aetiology of DFA is historic, with the key studies dating back to the 1970s. Most of the studies do not involve a UK population, which will affect the generalisability to the UK setting. Although many of the factors may still be relevant, changes in culture, technology, and differences within the present UK population, may have affected the aetiology of DFA within the modern-day UK population. Further research within this area would be beneficial.

1.4.1 Exogenous factors

Three learning pathways have been described by Rachman as a mechanism for acquisition of fear [14]. These include direct conditioning, indirect through vicarious learning (e.g. modelling), or exposure to threatening information. Research suggests that the direct conditioning theory is largely responsible for development of dental fear in children [15]. The study suggested that indirect learning processes were of minor importance in comparison.

1.4.1.1 Direct conditioning pathway

Rachman describes anxiety developing due to negative or difficult experiences via classical conditioning [14]. Pain elicits a fear response. This is a natural, or unconditioned response. Rachman explains how a painful dental experience, may subsequently link a neutral stimulus (such as the dentist) with the negative experience (pain). Following the painful dental experience, the dentist is then associated with the pain and therefore develops fearful qualities (a conditioned response). The stimulus producing the fear may not always be pain. It may include feelings of loss of control, issues with the dental professional, failures in treatment and feelings of embarrassment. Öst supported this theory when investigating how blood phobics and dental phobics acquired their fears [16]. In this study 69% participants

with dental phobia reported that their phobia stemmed from ‘conditioning experiences’. The drawbacks of this study are that it is over 30 years old, and studies a Swedish population, which may not be representative of current populations in other countries. In addition, it was based upon questionnaires and recall of historic events leading to recall bias. The study does not outline the inclusion and exclusion criteria. However, the results of the study are in-keeping with other similar studies.

There is evidence to suggest that not all children who have a traumatic dental experience go on to develop DFA. Davey et al describe the latent inhibition hypothesis [17]. This suggests that children who have a greater number of positive dental experiences prior to a negative experience are less likely to develop DFA. This theory is supported by Townend [15]. In this study of anxious and non-anxious children, the anxious children encountered their first traumatic experience earlier in life than non-anxious children. The non-anxious children also described the previous dentist as more empathetic, suggesting more positive dental experiences prior to the traumatic experience.

Ten Berge also support this theory [18]. Their study found that children with lower levels of DFA had experienced more check-ups prior to undergoing curative treatment, than children with high DFA levels. This suggests that children had greater ability to tolerate negative dental experiences after a history of non-invasive visits. The age and location of the study reduce its generalisability. The study took place across two practices with standardised protocols. The sample size of 401 participants was large, with an even gender split. The information was based upon a parent reported anxiety measure (questionnaire) and the information about historic treatment was taken from records which may not have been standardised. Limitations of parent-reported anxiety measures are discussed in section 2.6 and may not be a true representation of a child’s DFA.

1.4.1.2 Vicarious (Modelling) pathway

Rachman’s second pathway suggests that DFA can develop from observed anxious behaviours, commonly from the mother as the primary caregiver [14]. The child then copies this behaviour (modelling). This theory is supported by a structured review and meta-analysis in which the majority of studies confirmed a relationship between parental and child dental fear [19]. The review demonstrated that the relationship is most evident in children aged 8 and under. Due to the cross-sectional nature of the studies used, cause and effect cannot be

proven as other confounding factors cannot be controlled. However, the evidence is strong enough to show the importance of managing parent/carer anxiety.

1.4.1.3 Information pathway

Rachman's third pathway proposes learnt DFA as a result of hearing or seeing frightening information from home, school, media or known people (friends and family) [14]. The evidence to support this theory is limited. However, Bedi et al found that children knowing a greater number of people with DFA was a strong predictor for DFA in the child alongside the length of time since the last visit to the dentist [20]. This cross-sectional study involved a large sample of 1103 children across 8 different schools. The study attempted to standardise the protocol for completion of questionnaires between sites and a pilot took place prior to the study.

1.4.2 Endogenous factors

Endogenous factors cover the internal reasons for a child to experience DFA. Locket et al describes this as a 'constitutional vulnerability to anxiety disorders' [21]. This may include individual factors such as genetics, general anxiety, age, gender, personality traits and cognitive ability.

1.4.2.1 Genetics

Ray et al carried out a longitudinal study of 1480 Swedish twins (part of the Swedish Twin Study of Child and Adolescent Development) [22]. The study over two time points, three years apart, asked three key dental fear questions and an additional question on the intensity of the fear. The study showed that heritability of DFA was high in girls, but low in boys. They concluded that the result for boys may be due to lack of power, as fewer boys reported dental anxiety. The study also showed that intensity of dental fear was highly correlated in monozygotic, but not in dizygotic twins in both boys and girls. The authors concluded that genetic predisposition is involved in DFA development, leading to monozygotic twins experiencing very similar levels of fear. Dizygotic twins, being less genetically alike, are "less likely to share the constitution facilitating fear learning".

1.4.2.2 General anxiety

A review by Klingberg in 2007 identified five studies involving DFA and general fear [3]. A positive relationship between general fear and development of DFA was found in four of these studies. However, evidence is conflicting, and many studies identified in this review could not be included due to inadequacies in study design.

1.4.2.3 Age

Research around age and DFA can be conflicting. A number of studies identify higher levels of DFA in younger children [3, 24, 23].

Of greatest relevance to the UK, the 2003 and 2013 Child Dental Health Surveys (CDHS) oppose this theory, with highest prevalence of DFA identified in 12-year-olds, compared to those age 5, 8 and 15 years [25]. However, DFA in the younger age groups used parent-reported measures so are not directly comparable to those for the 12- and 15-year-old groups who used self-report measures. Comparing the 12- and 15-year-old child reported DFA levels would support the theory that DFA reduces with age.

A systematic review of DFA in children and adolescents globally pooled prevalence for different age groups and found higher prevalence of DFA in younger children, reducing with age; with prevalence of 36.5% for pre-schoolers, 25.8% for schoolchildren, and 13.3% for adolescents [26].

Other studies contradict this, such as Ten Berge et al finding highest DFA levels in age 8- and 9-year-olds when including ages 4 to 11 years [27]. Other studies have failed to find clear relationship between age and DFA [28, 29, 30].

This suggests that age, although an important consideration, may not be a key factor in development of DFA. Children should be assessed individually, irrespective of age, and persistent DFA over time should not be ignored.

1.4.2.4 Sex

Many studies indicate that females report higher levels of DFA than males. Most relevant to the UK is the UK Child Dental Health Survey [25]. This showed that boys were more likely to report low or no levels of anxiety ;31% of 12-year-old boys compared to 16% of 12-year-old girls and 44% 15-year-old boys compared to 28% 15-year-old girls. Girls were also more likely to report extreme dental anxiety. However as this is a self-reported measure of anxiety, it is unknown whether this is a true difference in prevalence, or a difference in willingness to report anxiety. In the same survey when looking at parental report on child anxiety in the younger age group we see a similar gender difference, with boys less likely to be reported as anxious. This is supported by other studies identifying females as having higher levels of DFA [3].

However due to use of self-reported measures it has been suggested that the gender differences may just be in the willingness to report, rather than the underlying DFA levels. A study by Townend et al suggested that males tended to underplay their worries about the forthcoming dental examination [15]. Duivenvoorden et al hypothesized that this may be due to expectation for males to be more stoic, however this study was based on the adult population so may not be generalisable to children [31].

This evidence highlights the importance of taking an individual approach to management of dental anxiety, taking account of observations of patient behaviour alongside any reported anxieties, as some DFA may be under-reported.

1.5 Prevalence of dental anxiety

Prevalence of dental anxiety in children varies throughout the literature. This may be due to differences in the measurement tools used, the populations studied, and the threshold scores used to define levels of anxiety.

The most relevant to UK is the Child Dental Health Survey (CDHS) from 2013 [25]. This is a national survey undertaken every 10 years, first starting in 1973. A random sample of children are selected aged 5, 8, 12 and 15 years, in England, Wales and Northern Ireland. The children are examined by trained and calibrated dental professionals. In 2003 the need for assessment of dental anxiety was identified. The 2003 survey asked a single question regarding emotions about attending the dentist. This was expanded upon in 2013 with by

including the Modified Dental Anxiety Scale (MDAS) within the questionnaire for 12- and 15-year-old children. For the 5- and 8-year-olds, parents were asked to rate their child's anxiety about visiting the dentist. They used a scale of 1-10, with a value of 1 being not at all anxious and 10 being extremely anxious.

The 2013 survey demonstrated that extreme anxiety was experienced by 14% of 12-year-old children, and 10% of 15-year-old children. An additional, 62% of 12-year-old children and 54% of 15-year-old children experienced moderate dental anxiety. This left only 24% 12-year-old and 36% 15-year-old children experiencing no or low levels of anxiety. On an individual item level, having a tooth drilled or having local anaesthetic injection were the two items on the MDAS that elicited anxiety most often. Parents overall reported lower levels of dental anxiety in the younger age group than the older children who self-reported. 50% of 5-year-olds and 55% 8-year-olds were reported having no anxiety. 26% 5-year-olds and 28% 8-year-olds were reported to have low anxiety when visiting the dentist. 22% 5-year-olds and 17% 8-year-olds were reported to have moderate to extreme anxiety when visiting the dentist. This indicates the widespread nature of DFA amongst children and young people within the UK, particularly among 8–16-year-olds, highlighting the need for interventions to manage this.

Global DFA prevalence was investigated by systematic review with meta-analysis by Grisolia et al [26]. The authors reviewed all observational studies of DFA between 1985 and 2020 and performed a meta-analysis. 50 studies were included and found a global DFA prevalence of 23.9%. The findings on age were converse to those found in the UK CDHS, with the global review indicating a higher prevalence of DFA within younger children than adolescents. However, the review identified that no study had high methodological quality, and recommended use of STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) in future observational studies of DFA.

Klingberg et al carried out a review of the literature published between 1982 to 2006 [3]. The review investigated DFA prevalence, and BMP and their relationship to other factors including age, gender, and temperament. Prevalence of both DFA and BMP of 9% was demonstrated, with a reduction in anxiety with age, in keeping with the later findings of Grisolia et al [26]. They found higher prevalence of anxiety in girls than boys. These differences in gender and age were also seen in the UK Child Dental Health Survey [25]. A large variation in prevalence between studies was demonstrated, varying from 5.7% to 19.5.

They also identified that children's self-reported prevalence ;13.5% to 19.5%; was greater than parent-reported measures (5.7%-6.7%). This may suggest that parents underestimate the anxiety children experience when visiting the dentist. The paper highlights limitations in methodological quality within the literature, and risk of bias. 79% of identified articles could not be used in the review due to inadequate measures, endpoints, or poor study design. Different studies used different anxiety measures, and different cut-off points for dental anxiety. This shows the difficulty in comparing and pooling data from studies and the low level of evidence available. The paucity of studies with rigorous methodology led the authors to recommend a need for more high-quality adequately powered studies in this area using reliable, validated anxiety measures.

Prevalence varies according to the different populations and age groups studied. Wogelius et al carried out a cross-sectional study of 6–8-year-old Danish children, investigating DFA and BMP [23]. DFA prevalence of 5.7% was identified and BMP were identified in 37.2% children who had dental treatment. BMP were observed more often in those with DFA. One of the methodological problems with this study was the use of parent-reported measures. The Children's Fear Survey Schedule-Dental Subscale was used. Ten Berg et al used the same scale was used for parent-reported measures, completing a large study of 2144 Dutch children aged 4 to 11 years [27]. 14% of the participants experienced levels of dental fear which may interfere with dental treatment. 6% had high levels of fear and 8% were at risk of developing dental phobia.

Taani DQ et al 2005 identified higher levels when using child-reported measures with Jordanian children. They found 42.9% of 12–15-year-old children experienced low to moderate levels of dental anxiety and 10% experienced high levels of dental fear [32]. This used a self-reported questionnaire modified from the by Dental Fear Scale (DFS) by Keinknecht et al [33].

These significant differences in prevalence from across the literature are likely due to differences in study methods, scales and endpoints used, accuracy of parent/patient reporting, along with population differences. The systematic review by Grisolia et al found methodological quality of current literature to be poor with high risk of bias [26]. It is therefore difficult to identify true DFA levels within a population. However, even the lowest identified levels indicate a clear need for methods to manage DFA, particularly when we consider the wide-reaching impact of this DFA.

1.6 Impact of dental anxiety

The impacts of DFA in children can be significant and extend far beyond the individual level. DFA can impact upon the child and their family, the dental professional, and the wider health system.

1.6.1 Influence of DFA on individuals

1.6.1.1 Impact on oral health status

Dental anxiety can have a significant impact on oral health and can result in higher levels of untreated dental disease.

Regression analysis of the Child Dental Health Survey 2013 indicated that DFA in children ages 5 and 8 years, had a significant impact on their own oral health, and impact on the child's family. Presence of DFA was a predictor for the child having decay experience ($p < 0.001$), active decay present ($p < 0.0001$) and signs of untreated oral infection ($p = 0.007$) [34]. Data was analysed from 4,916 participants and included parent-reported anxiety scores. Presence of dental anxiety was a statistically significant predictor of impact on family life, with previous GA for dental treatment being another predictor. Previous work by the same team suggested that children with higher levels of DFA are more likely to experience decay, likely to be infrequent dental attenders, and more likely to have treatment that carries greater risk, such as a general anaesthetic [35]. They also demonstrated that the oral health of children with DFA has greater impact on their family life than those with little to no DFA. These studies have limitations, including the use of parent-reported measures for dental anxiety and whether this accurately reflects the child's anxiety levels.

Klingberg et al 1994, demonstrated that children with BMP had more carious and fewer filled surfaces [3]. They were also more likely to be provided restorative treatments without local anaesthesia than those children without behaviour management problems.

A cross-sectional study of children aged 7-11 years in Turkey by Oba et al found that the Decayed, Missing and Filled surface index increased as DFA increased [36].

Wogelius and Poulsen showed that dental treatment due to toothache was associated with missed appointments, particularly for children with two or more missed appointments [37].

This may be due to the children only presenting when in pain. This may also be a factor in children with higher levels of DFA having more missing teeth [38].

Children with DFA report more frequent dental pain [37, 39]. This study also demonstrated that anxiety scores were higher among those with a toothache on the first appointment, possibly continuing the cycle of dental anxiety.

1.6.1.2 Avoidance of dental care

As mentioned above, DFA can lead to avoidance of dental attendance. This leaves children at risk of undiagnosed dental disease, pain, and infection. This is represented in the Child Dental Health Survey 2013, which shows 30% of 15-year-olds with extreme dental anxiety do not attend the dentist for a check-up, compared to 15% of non-anxious 15-year-olds [25]. There was no statistically significant difference in 12-year-olds, possibly due to parents still ensuring their child attends at this age.

This avoidance of dental appointments in anxious children is supported by other studies [3, 37]. This not only wastes health resources but also has an impact on children's quality of life as shown below. Wogelius and Poulsen 2005 showed an association between dental anxiety and missed appointments, however this association was relatively weak with an odds ratio of 1.28 for one or missed appointment. Their data did not show any differences this relationship over different age groups. However, Skaret et al found that missed appointments had nearly a linear increase from age 12 to 18 years [40]. This suggests that avoidance behaviour in children is likely to continue into adulthood.

1.6.1.3 Quality of Life

The CDHS found that two thirds of 12- and 15-year-olds had experienced at least one problem with their dental health over the three months prior to the study [25]. 15% of children had experienced toothache within the same timeframe. This highlights the impact of dental disease on quality of life (QoL).

Carillo-Diaz et al demonstrated that participants who reported a higher level of DFA tended to report lower emotional well-being as a result of their oral status [41]. The study showed

that those with more negative self-evaluation of their oral health experienced a greater emotional impairment resulting from their oral status. This was more significant in females than males, suggesting that females with high levels of DFA experienced poorer emotional well-being.

A questionnaire based cross-sectional study of 97 Finnish children aged 11-14 years by Luoto et al indicated that children with higher levels of DFA, had poorer oral health related quality of life (OHRQoL) with poorer social and emotional wellbeing [42]. However, this study specifically looked at children with cleft lip and palate, so generalisability may be limited.

Qualitative research by Morgan et al identified common themes between children and young people with DFA, including negative predictions about dental visits with anticipated pain, harm, and loss of control, negative psychological states such feeling shame, anger, embarrassment, fear. Although this mainly investigated their feelings around attending the dentist there were also reports of reliving traumatic experiences after their dental visits [43].

Looking at the adult population, a study by Vermaire et al assessed the difference in oral health related quality of life (OHRQoL) and health related quality of life (HRQoL) between adult patients with severe dental anxiety, and matched subjects without severe dental anxiety in the Netherlands [44]. They found statistically significant lower scores for OHRQoL in subjects with severe dental anxiety. This included all domains of the Oral Health Impact Profile assessment (OHIP14-NL) [45] which includes functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. They also found that high HRQoL was significantly less common in the group with severe dental anxiety. Extrapolating this to a population level, they estimated that dental anxiety in the Dutch population is likely to result in 74,000 disability adjusted life years (DALYs).

1.6.1.4 Long term consequences

Evidence suggests that children with DFA take this onto adulthood. In a study by Locker et al on anxious patients, half became anxious as children, with a further 22% developing DFA as adolescents [21]. Arch et al 2001 showed that children having general anaesthesia (GA) for dental extractions were more likely to remain anxious after treatment, with no change in

dental anxiety levels post-treatment, than those children having inhalational sedation (IHS) [46].

Mellor found that dentally anxious adults were less likely to attend for routine examinations [47]. The length of time since the last dental examination was a predictor for DFA, with longer intervals linked to greater DFA. This avoidance of dental visits leads to higher levels of unmet dental need, poorer oral health, attendance in pain and poorer long term oral health outcomes.

1.6.2 Influence of DFA on parents/carers

DFA in children can affect parents/carers in several ways, from time off work to emotional distress. The CDHS suggests that 1 in 5 parents had taken time off work due to their child's oral health [25]. The survey does not directly link this to dental anxiety, however the studies previously mentioned show that children with DFA are more likely to attend when in pain, thus leading to parental time of work.

A child with DFA puts additional stress on the parent/carer bringing the child to appointments. Hallberg et al found that parents had restricted or no strategies for handling the child's unwillingness, and this was often the reason for failed attendance [48]. Parents/carers are also likely to experience emotional distress when observing their child's fear and upset at the dentist.

1.6.3 Influence of DFA on wider society

1.6.3.1 On dental practitioners

Treating anxious patients can be inherently stressful. In a study of 216 Danish dentists 60% deemed dentistry to be more stressful than other professions and rated treating anxious patients as one of the five most intense stressors [49].

Dental practitioners can lack confidence in treating children with DFA and BMP. Klingberg et al show that children with BMP have higher levels of unrestored caries [7]. They also showed that for nearly half of the cases of BMP, the dentist chose to postpone treatment or took no measures to manage the BMP.

From a UK perspective, the survey of general dental practitioners by Hill et al indicated that 91% dentists find treating anxious patients stressful [50]. They also reported insufficient time available in practice for treating anxious patients and a lack of confidence in using these anxiety management techniques. They also felt that there would not be renumerated for this under NHS regulations.

This occupational stress can have significant implications. A cross-sectional survey by Goetz et al indicated higher risk of burnout for dentists perceiving higher proportions of dentally anxious patients in their practice [51].

1.6.3.2 On dental services

These effects on dental practitioners have knock on effect on dental services. Large numbers of children with DFA are referred on to secondary care due to lack of RA facilities in practice and financial considerations [52]. The high number of referrals to secondary care increase waiting times for both those with severe DFA, and those requiring secondary care for other reasons such as complex medical needs. Treatment in secondary care can also lead to patients travelling further for treatment, and to less efficient care [53].

1.6.3.3 Costs to NHS

Specialist and consultant services can be expensive to run, however, as these clinicians are salaried the costs can be difficult to calculate. However, care for children with DFA often involves pharmacological techniques which can be expensive. The estimated cost of one session of inhalational sedation is £273 and cost for treatment under general anaesthesia is £720 [54]. Given the date of this report, the cost is likely to have risen significantly since publication.

1.7 Measurement of dental anxiety

The high prevalence and significant impact of DFA in children demonstrate the need for accurate measurement of anxiety levels. Different tools may be useful in different settings, such as a tool measuring anxiety of an individual in practice to inform the dental team of their any specific worries, and the level of support they may need. They may be used for service

planning, indicating the levels of dental anxiety within a population to plan anxiety services appropriately. Researchers may need tools to identify anxiety within a population, to select participants in anxiety management studies.

The methods for assessing DFA in children can be broadly summarised into 3 categories:

- Direct observation; direct observation by dentist or researcher in a dental setting to assess the child's psychological state and by observing their behaviour response to the scenario, or via measurement of physiological response. The dentist-assessed method is not reliable, with research demonstrating only poor-moderate correlation between dentist-reported anxiety levels of a child, compared with child-reported anxiety levels [55]. As discussed above, BMP and DFA are not always directly connected. Measurement of physiological response such as comparison of heart rates during and pre-treatment may be more resource-intensive and less practical in many settings. There is also limited evidence around validity of these measures [56].
- Proxy measures of dental anxiety; parents/carers rate their child's level of dental anxiety via parent/carer-completed questionnaire. These measures may be more reflective of the carer's own dental anxiety than that of the child, with questionable validity of parent-reported measures [56].
- Self-report scales; DFA questionnaires completed by the child. Evidence demonstrates these methods have highest validity and reliability. Research by Aartman et al indicates from the age of 8 years, children are able to "report on all aspects of their health experiences" [56]. Several self-report scales have been developed. Some indicate "state" anxiety; how the child feels at that specific timepoint. Others, which can be more useful in DFA research assess "trait" anxiety assessing how a child would feel in a variety of different contexts or scenarios. It is important that the child understands the questions being asked, and the response options.

Porritt et al performed a systematic review of literature between 1998 – 2011 to identify and evaluate the different self-report measures of DFA used with children using three pairs of independent reviewers [57]. They looked at several aspects including concurrent validity, reliability, developmental validity (whether children had been involved in development and testing), and the specific aspects of DFA which the questionnaires assessed. The findings are summarised below:

Trait Anxiety Measures

The children's fear survey schedule dental subscale (CFSS-DS): A 15 item questionnaire related to dental situations and treatments, developed from the Fear Survey Schedule for Children, a longer questionnaire assessing children's fears and anxieties in various other situations [58].

Advantages	Disadvantages
Clear, established cut offs for anxious/highly anxious. High reliability. Used with a wide age-range of children. The most commonly use tool, used in 28 studies.	Some questions are less relevant to dental setting. No involvement of children in development of tool. Does not assess physical reactions, thoughts or behaviours. Some studies modified the questionnaire, making comparison of data difficult.

Dental fear schedule subscale short form (DFSS-SF): A shorter 8 item version of the CFSS-DS. Asks how frightened children would feel in each dental situation [59].

Advantages	Disadvantages
Improved relevance (items not relevant to dentistry removed (in comparison to CFSS-DS). Shorter, so quicker to complete than CFSS-DS. Clear, established cut offs for anxious/highly anxious. High reliability Used with a wide age-range of children.	No involvement of children in development of tool. Does not assess physical reactions, thoughts or behaviours.

Dental anxiety scale (DAS) and modified DAS: DAS is a 4 item measure, and modified DAS a 5 item measure asking how relaxed or anxious the respondent feels about different dental situations [60]. Has also been used in combination with the Facial Image Scale (FIS) producing the Combined Dental Anxiety Scale (COM-DAS) [61].

Advantages	Disadvantages
High reliability estimates. Explores situational triggers and physical reactions. Short compared to other measures.	May be less appropriate for use with children, as it was developed as a measure of dental anxiety in adults. No validity estimates for the measure when used with children. Does not assess unhelpful thoughts and behaviours associated with dentistry.

Modified child dental anxiety scale (MCDAS): An 8 item questionnaire, which includes 4 items based upon the original DAS. Assesses general level of dental anxiety and 7 specific situational triggers [62].

Advantages	Disadvantages
High internal reliability and validity. Children involved in development. Faces version (MCDASf) developed for use with younger children and those with limited cognitive functioning. Explores situational triggers and physical reactions.	2 questions on sedation and anaesthesia may limit applicability where child does not understand these procedures. Does not assess unhelpful thoughts, behaviours, or physical reactions.

Dental Fear Survey (DFS) and modified versions: DFS is a 27 item questionnaire developed for adults, with modified versions of 20 items, and later 15 items for children's responses. Assesses general dental anxiety and a variety of dental situations [63].

Advantages	Disadvantages
Explores situational triggers, physical reactions and unhelpful behaviours. Excellent internal consistency with children 8-18 years.	Does not assess unhelpful thoughts. Some triggers assessed may not be relevant to children.

Smiley Faces Programme (SFP) and revised SFP (SFP-R): Computerised measure with 7 item facial image scale asks children how they would feel in different dental scenarios [64, 65].

Advantages	Disadvantages
Children involved in revision of the piloted version. Interactive, so may be appealing to children.	Reliant on computer access. Does not assess unhelpful thoughts, behaviours or physical reactions.

Short version of dental anxiety inventory (S-DAI): A 9 item questionnaire asking level of agreement with statements on feelings/reactions in a dental scenario [66].

Advantages	Disadvantages
Explores situational triggers, thoughts, physical reactions and unhelpful behaviours.	Developed to measure dental anxiety in adults so format may be unsuited to children, particularly younger ages. No reliability or validity estimates for use with children.

State Anxiety Measures

Facial image scale (FIS): One item response with a set of 5 faces to indicate how they feel at that timepoint. Can be used as a standalone measure, or a response set for other measures [61].

Advantages	Disadvantages
Concurrent validity - correlation with Venham Picture Scale (VPS) Enables use with younger children and those with limited cognitive or linguistic skills.	Does not assess specific triggers, unhelpful thoughts, behaviours or physical reactions. May assess mood at a timepoint rather than anxiety. No reliability estimates.

Venham Picture Scale (VPS): Fully pictorial measure using 8 pictures with 2 cartoon boys. Child chooses which boy displays the emotions they are feeling [67].

Advantages	Disadvantages
Suitable for use with young children, and alleviates need for language skills. Internal consistency is high.	Some picture it is unclear what emotion is being conveyed. Does not assess specific triggers, unhelpful thoughts, behaviours or physical reactions. No information on validity of the measure. No established cut-offs for anxious/non-anxious.

The review found that many measures had limited focus, failing to investigate specific situational triggers for DFA. They also failed to fit with theoretical frameworks for DFA, therefore may miss some essential aspects of anxiety associated with a dental setting. This may lead to failure to identify, and understand certain aspects of DFA. Five of the measures had been primarily developed for use with adults, and so relevance to children may be limited.

The authors followed this up by developing a dental anxiety measurement tool, involving children in its development [68]. This is the Children's Experiences of Dental Anxiety Measure (CEDAM). The authors based the measure on the Five Areas cognitive behavioural model of anxiety as a theoretical framework, to ensure all aspects of DFA are assessed by the questionnaire [69]. This model represents the links between situational factors, unhelpful thoughts, unhelpful behaviours, physical symptoms and feelings, and how these can develop and maintain DFA. Qualitative interviews with children about their experiences of DFA informed the questions in the measure. These questions were linked to the different areas of the Five Areas Model. After cognitive pre-testing and piloting, a study was performed for reliability testing. The MCDAS was used as the gold standard measure for comparison assessing concurrent validity and indicated significant positive relationship between the two measures. Construct validity was assessed by comparing known anxious and non-anxious groups and was high for both MCDAS and CEDAM, with the dentally anxious group having higher scores on both measures. Test-retest validity was high for both MCDAS and CEDAM with intraclass correlation coefficients of 1.0 and 0.98 respectively. The responsiveness of the measure to change in levels of dental anxiety was evaluated by test with the MCDAS and CEDAM before and after an intervention was used to reduce their dental anxiety. Both measures were able to detect changes in dental anxiety after intervention.

Due to the CEDAM having high reliability; the involvement of children in its development, reflecting the outcomes they deem important; and that it analyses all aspects of DFA, this was chosen as the measure used in this study.

Since starting this this study a short form of the CEDAM has been developed; the CEDAM-8. This is an 8-item questionnaire in comparison to the CEDAM's 14-items. This is less time-consuming for the patient to complete, shows good reliability and response to change. The CEDAM-8 has not been used in this study as it was developed after the study had already started. This study also suggested a minimal important difference (MID) for the CEDAM-14, of −3.86 to provide a meaningful benefit to participants. This was calculated using an anchor-based method, analysing the average change in anxiety score for participants who answer "I feel a lot less worried" the question "Has how you feel about going to the dentist changed" since they used a self-help CBT resource. However the authors acknowledge that due to the

limited sample size of the study, the MID to be used with caution, and further testing of the MID is required.

1.8 Behaviour Management Techniques

1.8.1 Non-pharmacological techniques

Behavioural management techniques are aimed at modification of a patient's behaviour and thoughts. This aims to make the change from negative to positive behaviour, replacing disruptive behaviour with cooperation. It also aims to reduce anxiety and teaching new coping strategies.

A number of techniques have been described in the literature which are summarised by a literature review [70]. The strategies include gradual exposure, which includes Tell, Show, Do. This has been shown to work well by getting children familiar with the equipment and environment of a dental clinic in a relaxed and gradual manner [71]. The technique involves telling the child the procedure, for example: "We are going to polish your teeth with this special toothbrush"; showing them the equipment; using a polishing cup on their finger; following by carrying out the procedure; polishing the teeth.

Systematic desensitisation is a similar gradual exposure technique first described by Wolpe, which tends to be more focused on a specific stimulus which the patient has indicated as the source of their anxiety, e.g. needles [72]. The patient is gradually exposed to the stimulus using steps which may take multiple sessions. The technique for paediatric patients is described by Taylor et al [73]. The stimulus is combined with focused relaxation. This too has been shown to have positive effects on specific phobias [74].

Positive and negative reinforcement as part of behaviour shaping, are both based upon classical conditioning, as described by Pavlov [75] and operant conditioning [76]. Positive reinforcement is the strengthening of positive behaviour through rewarding the child with something of value to them. This can include verbal praise, stickers, special time spent with parents or extra time watching television. Use of this technique gradually leads the child to display more positive, cooperative behaviour and associate the dental environment with positive thoughts. Negative reinforcement involves the removal of an aversive stimulus when the desired behaviour is demonstrated. This can lead to aversive behaviour, for example, if

the child screams in the dental surgery they are allowed to go home. This may lead this negative behaviour to be demonstrated in the future.

Modelling is a technique by which the child watches someone else in the dental surgery in order to learn positive behaviours [77]. This works best when the model is of similar status to the child, for example the same age and gender. This can be helpful both with live modelling [78, 79] or using filmed modelling [80, 81].

Voice control is a technique which has been described as a therapeutic punishment procedure and so care needs to be used with this technique to avoid increasing the patient's anxiety and aversive behaviours [82]. As described by Brauer a sharp, loud, surprise comment such as "Open your mouth and stop crying" can regain the desired behaviour [83]. This technique may now be unacceptable to some parents/carers and clinicians. Alternative versions are described involving talking very quietly when a child is crying so that they need to stop crying to hear the clinician's voice [84]. This may be more acceptable to the child, clinician, and parent, and prevent negative impact on the dentist-child rapport.

Other techniques such as restraint and hand over mouth have been used in the past but are no longer acceptable techniques in the United Kingdom.

1.8.2 Pharmacological Techniques

Acceptable pharmacological techniques vary between countries and change over time. In children the common pharmacological techniques used are conscious sedation and general anaesthesia.

Conscious sedation is defined 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.' [85, 86, 87].

Methods of managing dental anxiety need to be carefully tailored to the specific patient and so one particular technique will not suit all. The same applies to pharmacological techniques. All patients need careful assessment to ensure that the method is appropriate to their physical

and psychological development [85]. Operators and assistants must have appropriate knowledge and training, and the facility must have local protocols and equipment to deal with medical emergencies and adequate access for emergency services.

In the UK, inhalation sedation with nitrous oxide/oxygen is the only standard technique for children under 12 years old [87]. Best practice includes carrying out patient assessment and consent for sedation at a previous appointment. This assessment should cover the medical, dental social and anxiety history of the patient. This should be recorded along with the ASA status, which is a physical status classification for medical comorbidities. It is also recommended that they have written and verbal instructions both pre- and post-treatment. The treatment itself involves administration of nitrous oxide/oxygen delivered through a nasal hood and titrated to effect. The machines used have several safety features which negate the possibility of delivering a hypoxic level.

Sedation using midazolam is also a "standard technique" in young people ages 12 to 16 years. The preferred techniques in this age group are inhalation sedation with nitrous oxide/oxygen or intravenous (IV) sedation with midazolam titrated to effect [87]. Although oral and transmucosal midazolam are considered standard techniques, these are only recommended for the rare occasions that IV sedation is not feasible. In addition to the above, IV sedation requires the availability of appropriate reversal agents, calibrated, labelled, and maintained equipment, supplemental oxygen, pulse oximetry and blood pressure monitors.

Evidence supports both the use of inhalation sedation with nitrous oxygen and the use of intravenous sedation with midazolam. A Cochrane systematic review has shown benefits of nitrous oxide over a placebo, however the evidence was reported to be low quality [88]. Further reviews into the use of oral and intravenous midazolam with children has supported their use but with weak evidence [88, 90].

Both inhalation sedation and GA for dental treatment are costly methods of managing children's anxiety. The cost per case for inhalation sedation has been estimated at £273 and for GA at £720 but is now likely to be higher [54].

1.9 Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) was developed in the 1960s by Aaron Beck and initially named “cognitive therapy” [91]. It has been adapted and has become more widely used over time. Treatment is based upon understanding the beliefs and behavioural patterns of patients and subsequent modification of the patient’s thinking to produce behavioural change.

It can be described as psychotherapy or “talking therapy” which aims to teach a person to identify unhelpful thoughts and challenge these, to change their responses to the thoughts and provide coping mechanisms. It is an evidence-based technique used with adults and children, for several mental health conditions. These include depression, anxiety disorders, stress, phobias, obsessive-compulsive disorder, and body dysmorphic disorders [92].

CBT has been demonstrated to be effective but as the technique has grown in popularity, waiting lists for psychologists has been a limiting factor in access to CBT. Different methods of delivering CBT with less reliance on psychologists have therefore been developed, to improve access. These methods include delivery via self-help books, online programmes, groups, and training other professionals in elements of CBT delivery. A meta-analysis and meta-regression of randomised controlled trials indicated effectiveness of self-help CBT for depression and stress [93]. This analysed interventions which were purely self-help, designed to be entirely carried out by the patient independent of a CBT practitioner and compared to guided self-help where patients had some minimal contact with a CBT practitioner. There was high level of heterogeneity, and so the random effects model and meta-regression analyses were used. The researchers found a higher effect size for guided self-help CBT than those using pure self-help (without support from CBT practitioner) but did not find evidence that the number of sessions impacted effect size. This evidence needs to be treated with caution due to risk of bias, and the use of short-term outcome measures. Limitations of this study were that the search strategy failing to include grey literature, hand searching or reference searches introducing publication bias. This was indicated in the paper by asymmetry of the funnel plot. The titles and abstracts were only reviewed by one researcher, so reliability was limited. The authors did not use a risk-of-bias-tool to appraise the studies and there was limitation in power of the study.

National guidance in England and Scotland recommends a stepped-care model for management of depression, anxiety disorders, obsessive-compulsive disorder and post-

traumatic stress disorder [92, 94, 95]. The guidance outlines assessment and treatment interventions and guides service provision to enable patients access to the most effective, least intrusive, and most easily delivered intervention for them. This considers severity of symptoms, persistence, and responsiveness to previous steps. This stepped-care model leaves specialists available for the more complex, higher need patients and for highly specialised treatment modalities, by managing the less complex patients with education and self-help psychological interventions in the earlier steps.

The traditional model of CBT uses highly technical language, specialised knowledge, and long delivery time of one-hour sessions for approximately 12-16 weeks [69]. Due to the constraints on access to psychologists, and clinical time a more accessible model of CBT was developed to combat these problems. The five areas model was originally commissioned by Calderdale and Kirklees Health Authority and is used by a wide range of professionals outside the profession of psychology [69]. It aims to use clearer language, without jargon in order to communicate the key CBT principles and interventions in a pragmatic way. The model considers five key areas, listed below, with accompanying example for dental anxiety:

- life situation, relationships, and practical problems; dentist finds new dental problems at each appointment.
- altered thinking/unhelpful thoughts: thinks dentist doesn't like them.
- altered emotions: embarrassed, angry, stressed.
- altered physical symptoms: heart racing, sweaty.
- altered behaviours: avoidance of dental appointments.

1.9.1 Use of CBT for adults with dental anxiety

The majority of CBT research has been carried out within the adult population, making a clear need for further investigation of this intervention within the paediatric population. A systematic review by Boman et al [96] identified 10 published randomised controlled trials. They found that dental anxiety was significantly reduced by CBT, and acceptance of dental treatment is improved.

A critical review carried out the same year by Gordon et al found similar results [97]. The authors identified and critically appraised 22 articles relating to treatment of dental anxiety in adults. They found evidence that CBT was effective at reducing dental anxiety of the short

and long-term including when only one session of CBT was provided. The review indicated that CBT was successful when delivered by psychologists and by dentists with appropriate training.

Both reviews indicated a low level of evidence around CBT in dentistry and recommended further research. The reviews are now 10 years old and need to be updated to incorporate new research. However, with a paucity of high-quality research on the topic, primary research may be the priority.

1.9.1.1 Psychologist-led CBT for dental anxiety

Outcomes of psychologist-led CBT are positive for enabling dental treatment. A study by Kani et al took a consecutive sample of 130 patients referred to the King's College London Dental Institute Health Psychology Service for CBT between 1 January 2009 to 30 May 2013 [98]. The researchers analysed the characteristics of this sample population, and the outcomes of treatment using psychologist-led CBT. Participants were assessed and provided CBT by a single psychologist. Dental treatment was provided by the dental team at King's College London Dental Institute. The majority of participants would usually have their dental treatment under conscious sedation. Baseline measures taken for participants assessed level of dental anxiety, Oral Health-related Quality of Life (OHRQoL), depression, generalised anxiety, suicidal ideation and intent, and alcohol use. The majority of patients were female (76%) with mean age of 39.9 years (range 16-91 years). Dental anxiety scores indicated 77% experienced dental phobia, with the remaining participants experiencing fear of a specific aspect of the dental experience. The most feared dental stimuli were drilling of a tooth, and local anaesthetic injections. Oral health had a negative impact on OHRQoL for 94% participants. This is more than double the 39% of the population recording impact on OHRQoL in the Adult Dental Health Survey 2009 [99]. Comorbid psychological conditions were present in the sample population including 37% with high levels of general anxiety, 12.3% with depression, 12% with suicidal ideation, and 3% reported recent intent to commit suicide. Alongside the characteristics of the adults accessing CBT in the service, the study reported the treatment outcomes. Of the sample population 79% had treatment without pharmacological management, 6% had treatment under sedation, 10% were deemed unsuitable for CBT, and 5% withdrew from CBT treatment. This study indicates a high proportion of adults accessing CBT for dental anxiety have comorbid psychological

conditions, which would benefit from referral and management. The intervention was time and resource intensive, with participants requiring an average of 5 visits of 1 hour for CBT prior to receiving dental treatment. The paper outlines the average cost per patient of £810. They discuss a possible reduction in long term costs, with patients being able to accept dental treatment without sedation in the future, but they do not investigate this, or carry out any long-term measure of dental anxiety. As the participants were all recruited from a dental hospital setting, Berkson (admission rate) bias may affect the outcomes.

Johren et al also found successful outcomes using psychologist-led CBT in a prospective study, but that the intervention was not effective for all participants [100]. A convenience sample of 160 participants who had avoided dental care for at least two years and demonstrated dental phobia were recruited from Bochum Dental Clinic. Participants were included if they were diagnosed with dental phobia, by self-report questionnaire, and structured diagnostic interview from a clinical psychologist. Treatment involved short-term psychological intervention over three sessions delivered by psychotherapy and behavioural therapy trainees. This was combined with a self-help brochure, and audio CD with relaxation techniques for participants to practice between sessions. 67% completed the psychological intervention. Of these, 86% saw the dentist for treatment, with 68% attending three or more dental appointments. Of those who did not complete the psychological treatment, slightly fewer (77%) attended the dentist afterwards, and 52% attended three or more dental appointments. The authors used attendance of three or more dental appointments as the outcome measure, and found the difference between groups was statistically significant, with superior results in those who completed the psychological intervention. The study also found that although duration of avoidance of dental treatment was not a predictor for success of CBT, the more severe the phobia, the more CBT sessions were required. However, the technique was not successful for all participants, as 30% of the phobic patients who finished the psychological therapy, were unable to complete their three dental appointments. The study does not describe the dentists who subsequently carried out treatment. As there is no control group, it cannot be determined whether the ability to cooperate with treatment was solely due to the CBT, or whether it was the effect of being treated by dentists with experience managing DFA.

A study by De Jongh investigated highly anxious patients attending a dental fear clinic [101]. Although the primary research aim was relating to trauma-related phenomena display by highly anxious patients, the study also analysed the success of a CBT approach. The authors

state that the operator treating patients was a dentist and clinical psychologist. A convenience sample of 38 participants received treatment-based CBT with graded exposure, and patients having treatment at the first appointment. There was no analysis of levels of dental anxiety after the intervention, but 79% patients received treatment at the first visit suggesting effectiveness. Only 45% were followed up to the second appointment due to time limitations. A number of patients postponed their second treatment, which could indicate residual anxiety. Of those who were followed up to the second visit 68% accepted dental treatment at this visit. There were limitations to the study, including a small sample size, attrition bias, and success of CBT intervention not being the primary outcome measure. Also, it assessed a very specific intervention in which the dentist was a clinical psychologist. The results therefore have limited generalisability.

A controlled trial comparing a psychologist-led CBT intervention both a sedation and a control group indicated a lasting reduction in dental anxiety and improved acceptance of dental treatment in the CBT group [102]. 50 patients were allocated to one of three different arms. The group allocated psychological treatment attended a 90-minute session with a psychologist a week prior to the dental visit, receiving stress and anxiety management training. They were given an audiocassette and written instructions for relaxation exercises to practice prior to the dental appointments. The pharmacological treatment group were given midazolam 30 minutes prior to their dental visit. The control group received no treatment for their dental anxiety. Anxiety levels were measured before treatment, immediately after treatment, and at one day, one week and two months later. The group receiving the psychological intervention showed reduction in dental anxiety from pre-treatment to one day after treatment. This reduction remained stable two months after treatment. In comparison, the pharmacological treatment group decreased immediately after treatment, with no further reduction over time. The results of the control group indicated slight reduction between the immediate post op measure and one day post-treatment. The only group with clinically significant change was the psychological intervention group. Physiological variables were also measured but saw no significant results. Of the original 50 participants, only 19 completed their course of dental treatment, with the majority (14) being from the psychological intervention group. Limitations of the study include 41 participants being excluded due to failing to attend for appointments or being unable to comply with treatment. There was no randomisation or sample size calculation. The high attrition rate leaves the

study at significant risk of bias. There are also ethical issues with a group receiving no treatment for their dental anxiety.

1.9.1.2 Dentist-led CBT

Use of dentist-led CBT for dental anxiety was compared to inhalation sedation and applied relaxation in a randomised trial by Willumsen et al [103]. 65 dentally anxious adult participants were selected by consecutive sampling from the Dental Faculty of the University of Oslo between January 1995 to March 1996 and randomly assigned to three groups. All participants were assigned ten weekly treatment sessions. All groups received some education about anxiety management which the authors described as “general non-specific treatment principles”. These included clear explanations of treatment, enhanced control techniques, relaxation with music, positive reinforcement and information about anxiety and avoidance. In the CBT group the participants received CBT at each visit from a dentist who had been trained by psychologists, and followed a specific protocol drawn up for the study. The group were given tasks to carry out between appointments and fearful thoughts were explored. The nitrous oxide (NO) group received a combination of NO and oxygen through a mask of their nose, with NO titrated on an individual basis up to a maximum of 55%. The “Applied Relaxation” (AR) group received education of early signs of anxiety and use of relaxation techniques as a coping strategy. They were provided with a tape for practising between sessions. Level of dental anxiety was assessed using self-report questionnaire at recruitment, start of treatment and end of treatment. Dropout rate was very low (4.6%) and the majority of participants across all groups found the treatment successful (96.7%). There were no between-group differences regarding treatment progression, and all groups recorded highly significant reduction in dental anxiety via the self-report questionnaires. This suggests no difference between the three techniques of CBT, nitrous oxide sedation and applied relaxation. However, the reduction in dental anxiety may have been attributable to the "general non-specific treatment principles” used, as participants rated this equally important as the specific anxiety treatments they received.

The authors followed the participants up after one year to assess level of dental anxiety, and attendance for further dental appointments [104]. Dropout rate was low at 4.8%, and 95% of participants had seen a dentist in the year since the trial with no difference in amount of non-attendance between groups. This suggests that reduction in anxiety in all groups was

maintained for 12 months. For the nitrous oxide group, 50% still received NO for their dental treatment after the trial.

Follow up at five years post-trial indicated the reduction in dental anxiety continued for the majority of participants, with no difference between groups [105]. 43 responded and completed follow up questionnaires, with a dropout rate of 30% at this five-year point. All participants had attended the dentist during the follow up period. Seven participants had scores at a level indicating dental anxiety, with no significant differences between groups. The majority (81%) across all groups reported that the dental anxiety treatment had been useful. As a randomised controlled trial, this study and follow up papers represents a high level of evidence, with a good length of follow up. The five-year follow up may be at risk of attrition bias due to the dropout of 30%, but at this timepoint this is a reasonable response. There may be selection bias (Berkson bias) due to all participants being recruited from a dental hospital, reducing the generalisability to other settings and possible reporting bias on the questionnaires where participants may have responded in the way to please the researchers. However, incorporating the acceptance of treatment supports this reduction in DFA.

Spindler et al investigated the effect of a brief cognitive-behavioural intervention provided by the dentists, at reduction of dental anxiety in a group of 104 dentally anxious participants [106]. The dentists were also psychotherapists. The participants were consecutively recruited from a private Danish dental clinic specialising in management of dental anxiety. The participants were split into two groups, with one group receiving the CBT intervention within one to ten days. The other group were placed on a waiting list, with this forming the control, for comparison of dental anxiety scores after four to six weeks without intervention. They then had the same CBT intervention after four to six weeks on a waiting list. Self-report dental anxiety questionnaires were used after randomisation, following their intervention sessions, and two years after the intervention. The waiting list group also filled out questionnaires just prior to their first appointment forming the control. The intervention, provided by the psychotherapy-trained dentists involved semi-structed interview addressing "cognitive, interpersonal and behavioural aspects of the participant's fears" along with embedding trust and sense of control in the participant. The participant was then exposed to the dental situation using a "hierarchy of feared situations". Using the waiting list group as the control, the study showed a larger reduction in levels of dental anxiety in the CBT intervention group, compared to those who had not yet received the intervention (waiting list

group). After both groups received the CBT intervention a clinically significant change in dental anxiety levels was seen in 59.3-64.4% of participants (for DAS and DFS measurements respectively). Attrition rate was high at the two-year follow up point, with only 43% returning the follow up questionnaires. The results of respondents indicated minimal change from post-treatment anxiety scores, indicating maintenance of treatment benefit, with no difference between groups at this timepoint. 68% participants attended follow up dental appointments in the two years after intervention. The large dropout rate at this two-year point however leaves this result at high risk of attrition bias. The design using a randomised controlled design is robust and represents a high level of evidence. Using a waiting list control improves equipoise, meaning all patients have access to treatment, with none being disadvantaged, However the expectation of CBT after their wait may have an effect on their DFA, potentially reducing the size of the difference between groups, underestimating the effect size.

Haukebø et al assessed whether the number of sessions of dentist-led CBT was a significant factor in reduction of dental anxiety, comparing one-session and five-session treatment with a waiting list control group [107]. 40 patients who had been diagnosed by clinical psychologist as dentally phobic and had avoided dental treatment for at least three years were randomised to three groups: one-session CBT, five-session CBT or waiting list control. Self-report dental anxiety scales (DAS and DFS) were completed pre- and post- intervention/ waiting list. After five weeks on the waiting list and completion of the control dental anxiety questionnaires the waiting list group were randomly assigned to either one-session or five-session CBT. Participants completed the anxiety questionnaires one week after treatment and again at one year follow up. The CBT intervention was provided by a dentist with specific training in CBT for dental phobia. The authors found that CBT had a significant effect on reducing dental anxiety scores compared to no treatment. The five-session CBT group demonstrated greater reduction in dental anxiety post-treatment than the one-session group, but after one-year there was no difference between these two groups, with both recording lasting reduction in dental anxiety at one-year. 77% participants attended further dental appointments during the one-year post-intervention, indicating success. Limitations to the study include a small sample size and risk of attrition bias. The use of only one dentist treating the participants may have led to bias, with the authors mentioning risk of “favourable bias towards the five-session treatment”.

1.9.1.3 Dental Nurse-led CBT

CBT provided by dental nurses has become more common for management of patients with dental anxiety. In the UK dental nurse-led CBT is provided in Sheffield, Bradford, and London. A service evaluation in Sheffield analysed this nurse-led dental anxiety management service (NDAMS) [108]. The NDAMS involved training two dental nurses in CBT methods, with support and regular supervision from a CBT therapist. The dental nurses ran a telephone triage service which explained the service to patients, took a thorough patient history, and signposted or referred them to the appropriate service. Patients with no urgent dental needs and no complex mental health conditions were offered CBT through the NDAMS. At appointments of 30-60 minutes duration the dental nurses delivered CBT for the patient's dental anxiety, including behavioural exposure interventions on the dental clinics when appropriate. On completion of the nurse-led CBT, the patients were offered dental treatment in the community dental services, accompanied by the same dental nurses. If patients felt they needed more support before being able to accept dental treatment they were referred for either psychotherapy or sedation. This mirrors the stepped care models for other mental health conditions [92, 94, 95]. The service evaluation involved measurement of dental anxiety and OHRQoL via self-report questionnaires before and after provision nurse-led CBT for 33 patients. A purposive sample of patients were also engaged in semi-structured interviews to explore their experiences of the intervention. Qualitative data was also gained via interviews and focus groups from the referring GDPs and from the dentists who treated the patients after the CBT. The service evaluation found a significant reduction in dental anxiety scores between the pre-treatment assessment and completion of the nurse-led CBT. OHRQoL scores also reduced indicating the intervention was successful for these patients. The qualitative data indicated that development of a trusting relationship, and effective communication were important factors in success of the intervention. However, patients also had concerns about leaving the service and returning to their regular dentist with concerns that their dental anxiety needs may not be met. Qualitative data from the professionals also included the importance of effective communication within the teams, and integration of services. They perceived the nurse-led CBT service to be effective in reduction of dental anxiety. As a service evaluation this provides a low level of evidence but does indicate the need for further research into nurse-led CBT.

1.9.1.4 Computerised CBT

Tellez et al developed and tested a computerised CBT (C-CBT) intervention for management of dental anxiety [109]. 151 participants who demonstrated dental anxiety via the MDAS questionnaire were randomised to either intervention group, who received C-CBT prior to their dental appointments, or waiting list control group, who attended dental appointments without any CBT intervention. The waiting list control group received the C-CBT later, after the study completion. Dental anxiety was measured using self-report questionnaire (MDAS) and via structured interview with a trained research assistant prior to treatment and 1 month after the dental appointment. A satisfaction score was also used. The C-CBT group attended 90 minutes early for their dental appointment, to undertake the C-CBT. The C-CBT was a single 60-minute session which included psychoeducation about dental anxiety, motivational interviewing and exposure exercises which enabled them to practice the coping strategies. This formed a series of videos. A research assistant was available to answer any questions. During their subsequent dental appointment, the participants were encouraged to utilise the coping techniques they had learnt for their dental anxiety. Attrition rate was high with 30% participants dropping out prior to the intervention. In total, 65% of those randomised, completed the study. Both groups saw reduction in dental anxiety, with the reduction being greater in the C-CBT intervention group. Authors found 83% participants were satisfied with the C-CBT. The authors proposed this as a less resource intensive method of providing CBT, without the need for a trained professional to provide it. This randomised controlled trial had a large sample size for good power, however the high dropout may have introduced attrition bias. The risk is that those who dropped out, are the participants who did not find the intervention helpful. The study overcome this by using intention to treat analysis.

1.9.2 Use of CBT for children with dental anxiety

Most research into CBT for dental anxiety involves adults and therefore cannot be directly applied to children. The lack of evidence around use of CBT in the paediatric population may be partially due to recruitment difficulties. Boman et al demonstrated difficulties when recruiting to a randomized controlled trial of adolescents aged 12-19 years with dental anxiety. Only 55 participants were enrolled of 138 possible eligible patients [110]. In this study 44 declined participation and 39 patients were excluded, showing the difficulties of research in this area.

CBT is currently not a commonly used modality of managing dental anxiety. This may be due to issues gaining access to this treatment. A retrospective audit by Simpson and Campbell in 2015 showed that only 25% of paediatric patients for whom dental treatment was successfully completed were treated with CBT [111]. Strøm et al showed similar figures in the paediatric population in Norway with 22% treated with systematic cognitive behavioural therapy [112]. The behavioural management technique used most commonly by dentists in this study was “Tell, Show, Do”.

Although the amount of high-quality research into use of CBT for children with dental anxiety is limited, the current studies have demonstrated that the technique is effective and well accepted by children.

1.9.2.1 Qualitative exploration of CBT with children

Shahnavez et al explored children’s’ experiences of psychologist-led CBT for dental anxiety, and the experiences of their parents [113]. Qualitative interviews were undertaken with 12 patients aged 7-19 years who had been treated with CBT for dental anxiety at Karolinska Institutet, Sweden between November 2010 to October 2012. One parent of each child was also interviewed. Prior to undertaking CBT all 12 patients had been diagnosed with “blood–injection– injury phobia” by a clinical psychologist. They were then provided between 4-15 sessions of CBT with an experienced, CBT-trained clinical psychologist. The interviews took place between 2-14 months after completion of treatment.

Thematic analysis highlighted an overarching theme of perspective shift, with three key elements of “mastery, safety and reduced fear”. Under the theme of “mastery”, children found gradual exposure to “fearful situations and instruments” to be highly effective in managing their anxiety. The also appreciated “autonomy and control”, with gradual increase in their confidence and increased involvement in decisions about their treatment. The theme of safety was broken down into “therapeutic alliance and changed appraisal”. This involved the children developing a positive relationship with, and a feeling of safety with the psychologist which transformed into feelings of safety with dental staff in the clinic. Children then changed their opinions on the risk of experiencing harm at the dentist, and started to feel the benefits outweighed the risks. The theme of “reduced fear” identified that CBT reduced the child’s anticipatory anxiety about attending the dentist, which they would previously experience in the day or days preceding dental visits. The behavioural and cognitive coping

strategies taught during the CBT helped them manage their dental anxiety. Eleven of the patients interviewed had accepted their previously feared dental treatment without pharmacological support. One patient had needed general anaesthesia for dental extraction despite the CBT. Parents and children reported reduction in their level of distress and dental fear after the CBT treatment, which supports the themes found in the study. This study gained rich data by using qualitative methodology. Limitations of the study include lack of acknowledgment of reflexivity, or bracketing, with the risk that the researchers' assumptions may have affected the direction of the interviews and the responses. The authors identified a need for further research, including research into different methods of providing CBT such as self-help, face-to face and internet-based. The need for randomised controlled trials investigating the use of these techniques in paediatric dentistry was also highlighted.

1.9.2.2 Quantitative studies assessing success of CBT with children

1.9.2.2.1 Psychologist-led CBT

A randomised controlled trial by Shahnavaz et al found that psychologist-led CBT was more effective at reducing dental anxiety and enabling acceptance of treatment than the control of treatment as usual [114]. 30 participants aged 7-18 years, with a diagnosis of dental anxiety or intraoral injection phobia were recruited from clinics in Stockholm. They were randomised into either CBT group or treatment as usual. Treatment as usual included standard behaviour management techniques, and pharmacological methods such as conscious sedation and general anaesthetic. The CBT group were provided ten hours of CBT over eight weeks, with psychologists experienced in delivering CBT to children with dental anxiety. Dental anxiety was assessed by self-report and parent-reported questionnaires, and via interview with clinical psychologist. Acceptance of dentistry was measured by Behavioural Avoidance Test (BAT). Although both groups showed some improvement, the CBT made superior, statistically significant improvements via all measures. 64% patients in the CBT group managed all stages of the BAT including acceptance of intraoral injection. Only 6% of the control group reached this level of cooperation. The differences were maintained over the 1 year follow up, with 73% CBT managing all stages of BAT compared to 13% control group. This indicates that psychologist-led CBT led to a lasting improvement in dental anxiety and cooperation levels. As the trial was advertised, there may be risk of selection bias if only those who felt they would benefit from CBT agreed to participate. The sample size is

relatively low, but comparable to other CBT studies, reinforcing the difficulties of recruiting to these CBT trials. Dropouts were accounted for using intention to treat analysis, reducing the effect of attrition bias. The study low sample size may have been due to the strict inclusion criteria, which the researchers used to gain high internal validity, reducing introduction of bias or confounders. However, this strict criteria reduces the external validity of the study, making the results less generalisable to other populations.

Psychologist-led CBT is reliant on access to clinical psychologists, and is expensive and time-consuming both for patients and professionals. For this reason, other methods of CBT provision have been explored.

1.9.2.2.2 Dentist-led CBT

As CBT becomes more popular, waiting lists for clinical psychologists increase. Dentist-led CBT may reduce the reliance on clinical psychologists and therefore remove this barrier to access.

The effect of dentist-led CBT on intraoral injection phobia in children aged 10 to 16 years was assessed via randomised delayed-intervention controlled trial [115]. A consecutive sample of 79 dentally anxious patients attending the Centre for Odontophobia clinic in Norway were screened for eligibility by two calibrated clinical psychologists. 67 participants with a diagnosis of intraoral injection phobia were randomised to two groups: immediate treatment group and waiting list control group. The CBT intervention comprised five sessions of up to 60 minutes with dentists specifically trained in use of CBT for intraoral injection phobia. For any participants who were able to accept intraoral injection during the five sessions, their treatment was completed at the same session. The remaining participants were scheduled treatment appointments with their regular dentist soon after completion of the CBT intervention. Their dentist was provided with information about the CBT intervention they had received. The immediate treatment group commenced CBT intervention the week after their psychologist interview. The waiting list group had their follow up interview (control) at the end of their five weeks on a waiting list, then commenced the same CBT intervention. Both groups were pooled for follow up assessments. The clinical psychologists performed diagnostic interviews at screening, post-waiting list for the control group, post-treatment for all participants, and again at one year follow up for all participants. A behavioural avoidance test (BAT) was performed at each of these timepoints by external dentists with specific

training in conducting this test. Information about the patients' success with receiving intra-oral injections after the intervention was obtained from the patient's regular dentist. A statistically significant reduction in dental fear and in behavioural avoidance was identified in the immediate treatment group. No significant difference was seen in the waiting list group who had not yet been provided CBT. After both groups received the intervention, there was a statistically significant reduction in all measures, with this being maintained at one year follow up. 70% participants were able to receive intraoral injections during CBT, with an additional 15% accepting a few drops, but not an effective amount. Of the 49 participants with additional treatment required in the following year, 69% were able to accept intraoral injections with their dentist. This suggests the dentist-led CBT intervention was an effective method for managing intraoral injection phobia in patients aged 10-16 years in Norway. The authors noted that the number of CBT sessions may be better tailored to the individual patient, rather than the prescribed five sessions. Limitations of this study included attrition bias from dropouts, although this was relatively low with response rates of 87% and 81% at post-treatment and one year respectively. There was also lack of calibration of the dentists carrying out the BAT. Of the dropouts from the study, two participants were diagnosed with ADHD one participant was diagnosed with autism. This may suggest that this CBT was not appropriate for some patients with these conditions, however the study does not detail whether their diagnosis was the reason for their dropout. The authors also do not mention that four patients who successfully completed the study had a diagnosis of ADHD. Further research is needed in this area.

Comparison of use of dentist-led CBT against nitrous oxide in managing dental anxiety for younger children was investigated by Kebiaee et al via randomised controlled clinical trial [116]. 45 children aged 3 to 6.5 years with diagnosis of moderate to severe dental anxiety who needed pulp treatment of at least one mandibular primary molar were recruited. All participants received dental prophylaxis and fluoride application at their first visit, during which dental anxiety was assessed via parent-reported questionnaire (CFSS-DS), and clinician-assessed dental anxiety and cooperation levels; Venham clinical anxiety scale (VCAS) and Venham Clinical Cooperation Scale (VCCS). The CBT group received went experienced a 16-minute CBT intervention which involved rapport building, modelling, education in relaxation and breathing technique, and a cognitive phase. The treatment (pulpotomy under local anaesthesia) was then immediately commenced with the children being reminded about the breathing technique. The conscious sedation group had rapid

induction N2O/O2 sedation for treatment, and the control group received conventional behaviour management techniques. A significantly higher reduction in dental anxiety and improved cooperation was seen in the CBT and conscious sedation groups compared to the control group. This suggests that CBT performs as effectively as conscious sedation at reducing dental anxiety in this age group, and that both techniques are effective in improving cooperation and reducing anxiety. All participants received inferior alveolar nerve blocks for treatment, and parents were excluded from the dental room during treatment. These may not be routine practice for all dentists who treat children, potentially reducing the generalisability of this study. Randomisation of participants should reduce the impact of confounding factors on the results, increasing the strength of evidence, however this study only assessed a specific treatment type (pulpotomy). This increases the internal validity of the study but reduces generalisability to other treatments. There was also no follow up to assess whether effects of the CBT intervention on DFA were maintained.

Although dentist-led CBT reduces reliance on psychologists, the method still places a burden on the dentists' time, which also comes at financial cost to either patients, or services. Alternative methods may reduce this by limiting the input needed from the dental professionals.

1.9.2.2.3 Computerised or recorded CBT interventions

A CBT type intervention provided via narrated story showed success when used with children aged 6-7 years. This investigation of cognitive behavioural schema was carried out by Aminabadi et al [117]. 80 children aged 6-7 years were randomised to either intervention or control group. The intervention group listened to a pictorial story about going to the dentist whereas the control group listened to a pictorial story about going to the barbershop. During subsequent dental treatment there was a significant decrease in pain perception and situational anxiety in the test group as assessed by self-report dental anxiety measures. In addition, the test intervention significantly improved the children's behaviour during treatment in comparison to the test group.

1.9.2.2.4 Self-help CBT approaches

Self-help methods of CBT may reduce the time burden for the patient and professionals by enabling patients to access CBT techniques and education in their own time. Self-help CBT for dental anxiety has been developed in the form of books [118] and guides [119].

Porritt et al (2017) developed a self-help resource for reducing dental anxiety in children. The resource development was guided by the Five Areas model of CBT as outlined in section 1.7 [69] which aims to teach and enhance coping skills. This was combined with a "person-based" approach by involving children with dental anxiety, parents/carers, and dental professionals in the development of the resource [120]. Through interviews and focus groups the children shared their experiences of dental anxiety and were asked what may help reduce their anxiety. These aspects were incorporated into the self-help guide with additional information for parents of dentally anxious children, and instructions for dental professionals on how to use the guides with their patients.

Following production of the guide a study was conducted to assess the feasibility of a trial to evaluate efficacy and cost-effectiveness [121]. 48 participants were recruited to the study which involved completion of dental anxiety and quality of life questionnaires before and after treatment followed by focus groups and qualitative interviews. The results showed a significant reduction in dental anxiety overall after use of the CBT resource as measured via questionnaires. It also showed reduction in anxiety relating to specific procedures, including "injection', "filling" and "tooth taken out". The study showed a small improvement in scores measuring the impact on health-related quality of life. Through the qualitative interviews children indicated positive experiences of using the guides, however they did identify some barriers to using the guides such as forgetting to complete them and concerns about the willingness of their general dentist to use it. The study found that although the guide is an acceptable intervention for anxious children, further evaluation of the resource is required. In addition, this study investigated dental professionals' acceptability of the resource. This identified benefits of using a self-help resource, but also questioned the feasibility within the time constraints of NHS clinics. In this study, 80% of the dental professionals interviewed about the resource had not used the resource with patients. The dental professionals recommended that the resource should be evaluated in different settings.

The participants were followed up via post 12-18 months after the patients' initial course of treatment [122]. Of the 50% of participants who responded, 82% had attended their general

dentist during this time and 56% of these had undergone treatment. 91% respondents felt less worried about dental visits than prior to using the guide. The sample size, although small is similar to other CBT studies. The qualitative element of the study provided rich data, but further information is needed with participants after use of the guides in different settings.

1.10 Rationale for this Study

DFA is a common reason for patients to be referred to the CDS. Analysis of referrals to the original study site of Rotherham NHS Foundation Trust CDS indicated an estimated 465 patients aged 8-16 years with DFA are referred to the service each year. Although the clinicians within the service are experienced in management of paediatric DFA using standard behaviour management techniques and pharmacological methods, this can be time-consuming for the patient and clinicians, and financially expensive.

As identified in the literature review, evidence suggests CBT methods may perform better than standard behavioural management techniques at reducing DFA, particularly for those with more extreme levels. Maintained reduction in DFA after CBT, and the learnt coping strategies may be utilised when a patient returns to their general dental practitioner (GDP). This may reduce the need for re-referral to the CDS, enabling patients to undergo further dental treatment with their GDP. This may reduce the burden on CDS which currently have lengthy waiting lists for treatment.

Use of the self-help CBT guide may enable patients to practice coping strategies between appointments, saving time in the clinical setting. Therefore, it was necessary to test the intervention within the CDS setting. Quantitative data on the effectiveness of the CBT intervention, and qualitative exploration of the acceptability of the CBT resources was needed.

Chapter 2 Aims and Objectives

2.1 Aim

To determine whether use of a self-help Cognitive Behavioural Therapy (CBT) intervention reduces dental anxiety and is acceptable to dentally anxious children aged 8-16 referred to Mid Yorkshire Hospitals NHS Trust Community Dental Services.

2.2 Objectives

- Assess whether dental anxiety is reduced following the self-help CBT intervention
- Compare health related quality of life before and after the self-help CBT intervention
- To investigate the acceptability to children of the self-help CBT intervention
- To investigate the acceptability to dental professionals of the self-help CBT intervention

2.3 Research Questions

Does the use of a self-help CBT intervention reduce dental anxiety in children aged 8-16 years, referred to Mid Yorkshire NHS Hospitals Trust Community Dental Services?

What is the acceptability of the self-help CBT intervention to children and to dental professionals?

Chapter 3 Methods

3.1 Study Design

3.1.1 Overview

This mixed methods clinical study evaluated the use of a CBT self-help guide with children with dental anxiety. The study involved two phases. This thesis reports on phase 1. Phase 2 will be completed out with this thesis and published separately.

Phase 1 was a quantitative investigation of the CBT resources. Phase 2 involved a sample of the participants completing a structured diary and undertaking qualitative interviews to explore how the CBT resource was used, and how well it was accepted. It also included qualitative interviews with the dental professionals to assess the acceptability of using the CBT resource, the benefits, and the barriers to its use.

3.2 Phase 1

3.2.1 Phase 1 Study Design Overview

This involved a sample of dentally anxious patients aged 8 to 16 years, using the CBT self-help intervention whilst undergoing a course of dental treatment. Their dental anxiety was measured using validated self-report dental anxiety questionnaires before and after treatment and again 3 months after treatment.

The study was commenced in Rotherham NHS Foundation Trust CDS. Due to the impact of the COVID-19 pandemic the service was no longer able to support the study. Following a pause during the peak disruption of the pandemic, Mid Yorkshire NHS Hospitals Trust CDS was added as a new site.

Children were asked to complete a questionnaire at three timepoints; baseline (T1), after the first treatment visit (T2) and 3 months after treatment completion (T3). The questionnaire contained two measures:

1. The CEDAM - a reliable and valid measure of child dental anxiety [68]
2. The Child Health Utility 9D (CHU9D) - a reliable and valid measure of child quality of life [123]

Both the CEDAM and CHU9D were chosen due to their child-centred development, which involved children in the design of the measures. The CHU9D is a preference-based measure of HRQoL which has been validated for use with children aged seven to seventeen years and therefore appropriate for the participants in this study.

3.2.2 Population Sample

3.2.2.1 The Sample

All new referrals for children aged 8-16 years to Rotherham NHS Foundation Trust CDS and later, Mid Yorkshire NHS Hospitals Trust CDS were assessed to identify dental anxiety from the details provided in their referral letter. Consecutive sampling technique was used, to include all patients aged 8-16 years old who were identified as dentally anxious, attending Rotherham NHS Foundation Trust CDS, or Mid Yorkshire NHS Hospitals Trust CDS, for dental treatment during the study period.

3.2.2.2 Inclusion and Exclusion Criteria

Inclusion criteria:

- Children aged 8-16 years with dental anxiety
- Children and parent consenting to take part in study
- Children requiring operative dental treatment: e.g. restorations, extractions, root canal treatment
- Children requiring at least 3 separate dental appointments

Exclusion criteria:

- Non-English-speaking patient and parent
- Children with a severe disability which limits their ability to undertake dental treatment without pharmacological approaches

- Fewer than 3 appointments required to complete treatment
- Children with an acute dental problem requiring urgent treatment

3.2.2.3 Sample size

The sample size calculation was based on a previous study [121] and calculated for analysis using a repeated measures ANOVA with three time points.

Calculation:

alpha = .05

power = .95

effect size = .25

correlation amongst repeated measures = 0.5

Sample size required = 43

To allow for a dropout rate over three time points of 40%, the target for recruitment was increased to 75 participants.

3.2.3 Permission and Funding

Ethical approval was sought from the National Research Ethics Committee and Health Research Association for the trial at Rotherham NHS Foundation Trust CDS. The REC reference number for the study was 19/LO/0303, and IRAS project ID was 252388 (appendices A and B). A non-substantial amendment was submitted for the addition of Mid Yorkshire NHS Hospitals Trust CDS as a site.

Approval of capacity and capability was gained from Rotherham NHS Foundation Trust Research and Development team and subsequently from Mid Yorkshire NHS Hospitals Trust Research and Development team when added as an additional site (appendices C and D).

Research funding was secured from the Society for the Advancement of Anaesthesia in Dentistry (SAAD) and research support from NIHR Clinical Research Network.

3.2.4 CBT Self-help guide

Child/Young person

The CBT self-help guide was developed by the University of Sheffield [119], with input from children, adolescents, parents and members of the dental team. See section 1.9.2.2.4 (page 40) for details on development of the guide, and preliminary testing.

The guide is available in booklet and online versions. All participants in the study were provided a hard copy booklet, but also signposted to the online version to use if this was their preferred method of engaging.

The guide includes the following CBT elements:

- Acknowledges the concerns that children may have.
- Provides factual information about the dental team, equipment and basic dental procedures, to reduce the child's fear of the unknown and address some concerns they may have.
- Provides coping mechanisms for children to use: encouraging them to change their way of thinking, talking things through with others, distraction techniques and breathing exercises.
- Encourages children to ask questions to increase their feeling of control.
- Provides a methods of conveying their concerns and increasing their feeling of control through the "message to the dentist", highlighting their worries, stating what they would like to happen at the appointment and things they would not
- Ensures that a stop signal is decided upon to provide the child with reassurance, and improve communication and the patient-dentist relationship.
- Encourages reflection after the appointment.
- Suggests forms of positive reinforcement, such as small rewards after a successful visit.

Website for resources: https://llttf.com/home/dental-anxiety/.

Parent guide

In addition to the children's guide, an additional information leaflet is provided to the parent/carer. This enables the parent/carer to be involved, and be aware of how to manage their own anxiety, and the impact this anxiety can have on their child. The information educates them on ways they can help their child manage their dental anxiety and play an active part in supporting them. This was also provided as a hard copy information sheet, with additional signposting to the website.

3.2.5 Participant and parent information sheets

Information sheets were provided to the parent and participant to provide information about the study, welcoming questions, and inviting them to participate in the study. These information sheets were adapted from those used in pilot studies [121]. Two different participant information sheets were provided for the different age groups of 8-12 years, and 13-16 years, to ensure they were age appropriate. Appendices E, F and G.

3.2.6 Patient assent and parent consent forms

It was important to gain informed consent from the parents and assent from the participants. For this reason the participant information sheets were sent two weeks prior to the patient appointment via post and/or email. This ensured the child had sufficient time to read and understand the research. These were adapted from those used in other studies [121] and were produced to be age appropriate. The child had the opportunity to ask questions, or to have their parent ask questions at the new patient visit. They then completed their assent form if they were happy to take part.

The parent also received the information sheet in the post prior to their first visit, to enable sufficient time to read about, and understand the research. They then signed the consent form at the new patient visit if they were happy for their child to take part. It was clear on the information sheet and consent/assent forms that the child could withdraw from the study at any time, and that there was no pressure to take part (appendices H and I).

3.2.7 Questionnaire design and data collection

3.2.7.1 Patient demographic data

Data was collected to assess the following variables: sex; age; ethnicity; home postcode (for assessing the level of deprivation of the area in which the participants live using the Index of Multiple Deprivation); case mix score (a descriptor used for all patients treated in the community dental services, which calculates the complexity of a patient's needs based upon their ability to communicate and cooperate, medical status, oral risk factors, access to oral care and legal and ethical barriers to care); previous dental history and treatment carried out during the study. This data was collected by the principal investigator.

3.2.7.2 Measurement of Dental Anxiety and Health Related Quality of Life

Data was collected by validated self-report questionnaires (CEDAM and CHUD9) completed by children in a quiet, private room prior to their new patient assessment [125]. The CEDAM is a 14-item measure of dental anxiety. The CHU9D is a 9-item validated measure of health-related quality of life (HRQoL). The combined questionnaires took an estimated ten minutes to complete.

The questionnaires were collected by the treating dentist and kept in a folder during the clinical session. At the end of the sessions these were transferred to a secure locked cabinet in a locked room at Mid Yorkshire NHS Hospitals Trust CDS.

3.3 Materials and Methods

3.3.1 Recruitment and sampling

Recruitment timeframes were based upon referral numbers to Rotherham NHS Foundation Trust CDS. One of the CDS clinics in Doncaster clinic received between 9-17 referrals per month of children aged 8-16 years under the category of behaviour management with the majority due to dental anxiety. The mean number of referrals per month was 13 patients. This did not include patients with dental anxiety referred in through other categories. In addition to this the two other CDS clinics receive a similar number of referrals. This suggested an estimated annual total of around 465 referrals for patients aged 8-16 years. These data suggested that the required sample size was achievable within a six-month period. Due to

staffing levels in Rotherham NHS Foundation Trust CDS initial recruitment was slower than anticipated, followed by the COVID-19 pandemic suspending the study. Mid Yorkshire NHS Hospitals Trust CDS was therefore recruited as a new site for recruitment.

3.3.1.1 Identification of participants

All new referrals aged 8-16 years were assessed to identify dental anxiety from the details provided in their referral letter. They were then sent the parent/carer and participant information sheets with their appointment details in the post (appendices E, F and G). A note was placed on their electronic record to record that the research information had been sent and their details were recorded in the participant recruitment logbook to enable follow up.

3.3.1.2 Approaching and recruiting participants

At the new patient assessment appointment, the child and parent were invited to take part in the study and any further questions were answered.

Consent to take part in the study was gained both written and verbally from the parent and assent from the participant at this appointment (appendices H and I). Participants were then given a baseline questionnaire containing the CEDAM and the CHU9D to complete prior to the new patient assessment.

3.3.2 Procedure

The following process was followed from participant identification to completion. This was summarised in a flow chart.

Appointment 1:

- At the new patient assessment appointment, those who met the inclusion criteria and had received the research information were invited to take part in the study.
- Written consent and assent to take part in the study was gained (appendices H and I).

- Participants were given a baseline questionnaire to complete including the CEDAM and the CHU9D in a quiet, private space (T1).
- The dentist carried out the new patient assessment and assessed eligibility for inclusion in the study.
- The dentist provided the participant with the self-help CBT booklet "Your Teeth, You are in Control" and discussed how it would be worked through over the course of treatment. They were also directed to the online version of the resource.
- The child was asked to complete the "Message to the dentist" prior to the next visit.

Appointment 2:

- The dentist went through the "Message to Dentist" in the CBT booklet to explore what the participant would and would not like to happen and their chosen coping action plan.
- The dentist and participant agreed what stop signal was going to be used.
- Treatment was carried out as normal.
- The dentist outlined the exact plan for the next visit.
- The participant was asked to complete the feedback pages in CBT booklet for discussion next visit.
- Participants completed the questionnaire again (CEDAM and CHU9D) in a quiet, private space (T2).

Appointment 3:

- The dentist reviewed the CBT feedback with the participant to confirm the coping plan, stop signal, and agreed plan.
- Treatment was carried out as agreed with participant.
- Further treatment appointments (if required) were undertaken with the same dentist, this was repeated for as many appointments as required.

Final appointment:

- Participants were discharged to their GDP with an explanation that the self-help CBT intervention was used for assisting the patient with their dental anxiety. The letter included a link to the resources.
- Demographic information and details of treatment carried out was collected at the end of treatment from the clinical notes by the Principal Investigator.

Three-month review with GDP:

- Participants were sent the questionnaire a third time at three months after treatment completion (T3).
- Participants were provided with a £10 voucher as a thank you for their participation.

3.3.3 Statistical analysis

The data was entered into an electronic database: Statistical Package for the Social Sciences (SPSS). It was analysed using descriptive statistics with changes in CEDAM and CHU9D scores analysed using a repeated measures ANOVA with 3 time points.

3.4 Ethical considerations

Participant confidentiality

Participant confidentiality was ensured by using a participant number on study documentation, with no patient identifiable data on questionnaires.

The data was transferred to a password-protected desktop computer in a secure room within the University of Leeds, School of Dentistry. Participant personal data was limited to basic demographic information and stored under the participants' study number for anonymity. Manual files of recruitment logs and consent forms with the study numbers of participants were stored in a separate secure location within a locked drawer within the Community Dental Services.

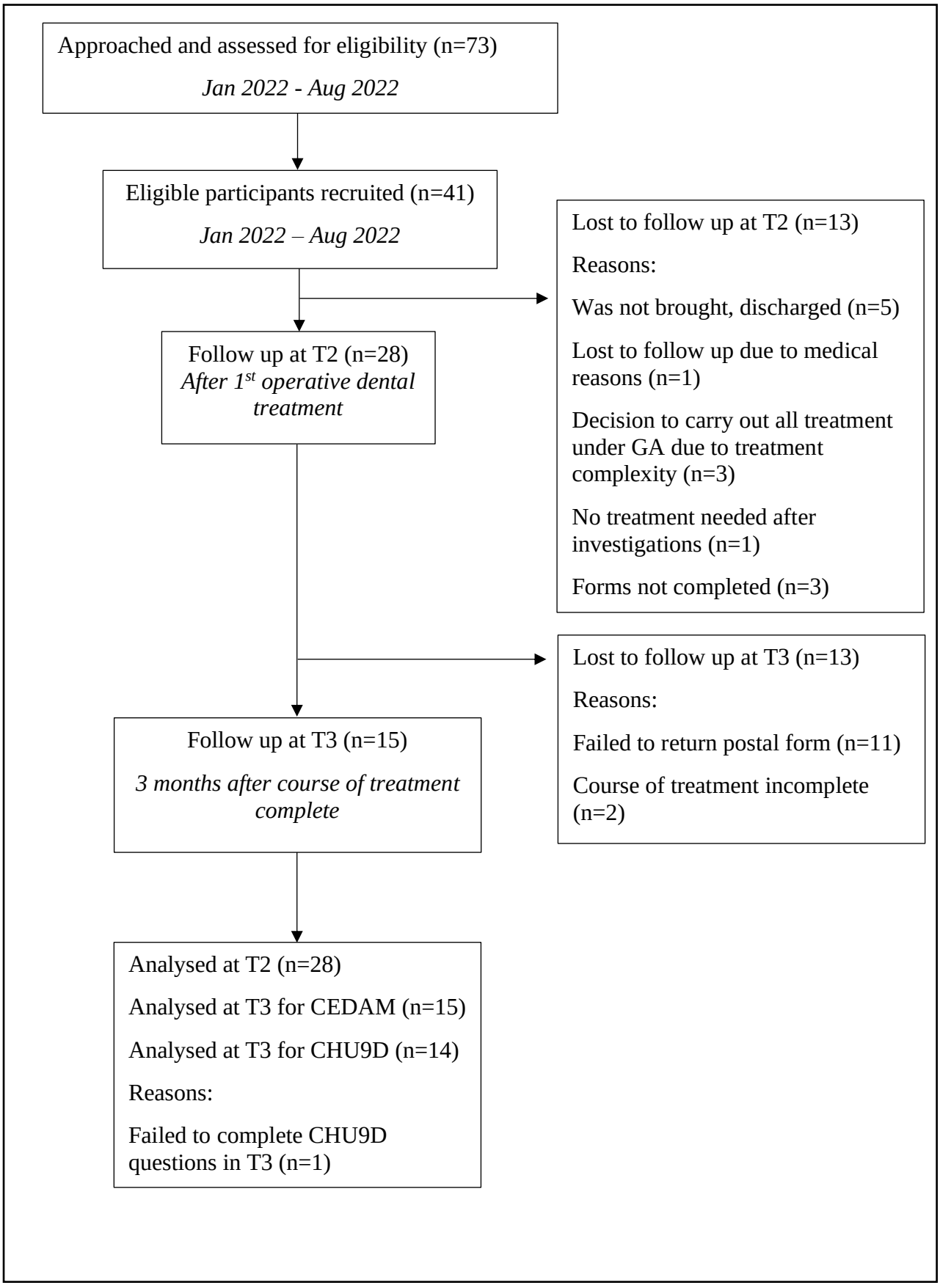
All research data generated by the study will be kept for five years after study completion before being destroyed.

Participant safety

It was not anticipated that participants would feel distressed during the course of the study and every effort was made to ensure patient comfort and confidence.

Chapter 4 Results

Figure 1 CONSORT Flow chart



4.1 Demographics of recruited participants

In total 41 participants were recruited to the study. Table 1 shows demographic details of the participants. The mean age was 11.0 years old. Age was skewed to the lower end of the range studied, with nearly 75% participants in the range 8-12 years. Sex was relatively evenly distributed, with slightly higher percentage of males than females, and one non-binary participant. Ethnicity of participants was nearly 90% White British. Three participants were Asian Pakistani, one participant other Asian background (Iraqi) and one participant other White background (Portuguese).

Overall, close to 90% of participants were living in the 50% most deprived areas of England as per the Index of Multiple Deprivation, with about 30% living in the 10% most deprived areas of England. No participants live in the least deprived decile.

Table 1

Variable	N	%
Age		
8-12 years	30	73.2
13-15 years	11	26.8
Mean age 11.0 years		
Age range 8-16 years		
Sex		
Male	23	56.1
Female	17	41.5
Non-binary	1	2.4
Ethnicity		
White British	36	87.8
Other White Background	1	2.4
Asian Pakistani	3	7.3

Other Asian Background	1	2.4
Index of Multiple Deprivation (Decile)		
1 (most deprived)	12	29.3
2	7	17.1
3	4	9.8
4	7	17.1
5	6	14.6
6	0	0
7	1	2.4
8	2	4.9
9	2	4.9
10 (least deprived)	0	0

4.2 Dental and Medical History of Recruited Participants

Tables 2 and 3 show the dental and medical history of the recruited participants. For most participants (87.8%) caries was their main dental diagnosis (n=36). Five percent (n=2) had dental trauma, five percent (n=2) dental anomalies and only one patient (2.4%) had a main diagnosis of a soft tissue condition.

Only ten percent of participants (n=4) had been seen in the CDS prior to their new referral, but 15% (n=6) had experienced previous dental GA. Twenty percent of participants (n=8) had successfully received local anaesthetic in the past. None of the participants had previous experience of inhalation sedation.

Overall, 80.5% of participants were normal healthy patients (ASA 1) with no systemic disease. Twenty percent had mild systemic disease (ASA 2). No participants in the study had

more severe systemic disease (ASA 3 or above). Fifteen percent of patients recruited to the study were autistic or had ADHD.

The number of decayed, missing and filled permanent teeth (DMFT) per participant ranged from 0-11 with a mean of 3.2 For primary teeth (dmft) the range was 0-8 with a mean of 3.8. Within this score the majority were carious teeth (d/D) with only five participants having filled teeth and no participants having missing teeth at time of referral. For those with caries the average number of carious permanent teeth per participant was three. For those with caries in primary teeth the average was five carious primary teeth per participant.

Case mix score for each participant was calculated. The score for the recruited participants ranged from 3, indicating some complexity, to 20, indicating severe complexity. Mean complexity was 13.6, within the moderate complexity category.

Table 2 Medical and dental history of participants

Variable	N	%
ASA Grade		
1	33	80.5
2	8	19.5
Additional needs (ADHD, Autism)	6	14.6
Main Dental Diagnosis		
Caries	36	87.8
Dental anomaly	2	4.9
Soft tissue condition	1	2.4
Trauma	2	4.9
Previously seen in the Community Dental Services	4	9.8

Previous Dental General Anaesthetic	6	14.6
Previous Inhalation Sedation	0	0
Previous Successful Local Anaesthetic	8	19.5

Table 3 DMFT and Case Mix Scores

Variable	Mean	Mode	Median	Range
DMFT	3.15	2	2	0-11
dmft	3.81	3	0	0-8
Case Mix	13.6	15	9	3-20

4.3 Details of Treatment

In total, five (12.2%) participants were not brought (WNB) to their follow up treatment appointments and were discharged. One (2.4%) participant was lost to follow up due to medical conditions, and one (2.4%) participant did not need treatment after further investigations. Three (7.3%) participants required treatment only under GA due to complexity of treatment. Of those who completed treatment, around two thirds (68.3%) had no appointments cancelled or to which they WNB. Three participants WNB or cancelled one appointment and another three WNB or cancelled two appointments. One participant WNB or cancelled four appointments during the course of treatment.

Of those who completed treatment, more than half participants accepted local anaesthesia (LA) during their course of treatment (61%). Just over one third of participants (36.6%) required inhalation sedation (IHS) with nitrous oxide for all or part of their treatment. Some participants required general anaesthesia (GA) for part of their treatment (17.1%).

Approximately a fifth of participants had some teeth treated without LA using Hall Technique crowns during their treatment (19.5%).

Table 4 Details of treatment

Variable	N	%
No. WNB/Cancellations		
0	28	68.3
1	3	7.3
2	3	7.3
4	1	2.4
LA used during treatment	25	61
Treatment under IHS	15	36.6
Treatment under GA	7	17.1
Treatment without LA (Hall crowns)	8	19.5

Some participants who accepted part of their treatment under local anaesthesia needed more complex treatment under inhalation sedation or general anaesthetic, hence the total numbers in the table.

4.4 Changes in Dental Anxiety

Baseline T1 questionnaires were completed by 41 recruited participants (figure 1, page 53). Dropouts due to children not being brought to follow up appointments, failure to complete forms and changes in treatment plans led to 28 participants completing the T2 questionnaire. The return rate of T3 questionnaires was lower, with 15 participants returning T3. One of these participants had left questions in the CHU9D blank, therefore 14 responses were included in the statistical analysis of this measure at T3.

As the data met the assumption of normality, a repeated measures analysis of variance (ANOVA) was used for the 15 participants who completed T3 CEDAM questionnaire. This indicated a statistically significant reduction in dental anxiety measured by the CEDAM. Reduction between initial assessment and after using the resource (T1 to T2) was -2.2. The change between the first treatment visit, and 3 months after completion of treatment (T2 to T3) was -1.1. This result was statistically significant with a p value of 0.001.

Table 5 Repeated Measures ANOVA for CEDAM interval score at T1, T2, T3 (n=15)

Timepoint	Mean	Standard Deviation (SD)
T1	22.1	2.9
T2	20.0	3.2
T3	18.9	3.2

p = 0.001

A paired t-test was used to analyse the changes between initial assessment and after using the resource (T1 to T2) for the 28 participants who completed T2 but failed to return T3 questionnaires. The paired t-test indicated a reduction in CEDAM score of -2.4 which was statistically significant (p <0.001).

Table 6 Paired t-test for CEDAM interval score at T1, T2 (n = 28)

Timepoint	Mean	Standard Deviation (SD)	Mean Difference	95% Confidence Interval of the Difference
T1	22.3	2.6		
T2	19.9	2.9	-2.4	-1.2 to -3.5

p value <0.001

Change in dental anxiety since first visit to the clinic and since using the CBT self help guide

Question 15 assessed the participants' change in feelings about going to the dentist since their first visit to the dental clinic. At T2, 35.7% participants felt a little less worried since visiting the dental clinic, and 39.3% felt a lot less worried. For 15% participants their feeling had not changed since their first visit, and 10.7% felt a little bit more worried since attending. All of the participants who were a little more worried at this point subsequently had part of their of treatment plan completed under inhalation sedation.

By three months after treatment, no participants felt more worried about going to the dentist. 23.1% indicated that their feelings had not changed since their first visit to the dental clinic, and 77% felt less worried. 30.8% felt a little less worried and 46.2% felt a lot less worried.

Table 7 Frequency table for question *"Has how you feel about going to the dentist changed since your first visit to the dental clinic?"*

	T2		**T3**	
Answer	**Frequency**	**%**	**Frequency**	**%**
I feel a lot more worried	0	0	0	0
I feel a little bit more worried	3	10.7	0	0
My feelings have not changed	4	14.3	3	23.1
I feel a little less worried	10	35.7	4	30.8
I feel a lot less worried	11	39.3	6	46.2
N	28	100.0	13	100.0

Question 16 assessed the participants' change in feelings about going to the dentist since they started using the green booklet (CBT guide). For 28.6% participants at T2 their feelings had not changes since using the CBT guide, 7.1% felt a little bit more worried since using the guide and 64.3% felt less worried since using the guide. Just over one-third (35.7%) felt a little less worried and 28.6% felt a lot less worried.

By three months after treatment, no participants felt more worried about going to the dentist since using the guide. Around one-quarter (23.1%) indicated that their feelings had not changed since their first visit to the dental clinic, and 77% felt less worried. Nearly one-half (46.2%) felt a little less worried and 30.8% felt a lot less worried.

Table 8 Frequency table for question *"Has how you feel about going to the dentist changed since you started using the green booklet?"*

	T2		T3	
Answer	**Frequency**	**%**	**Frequency**	**%**
I feel a lot more worried	0	0	0	0
I feel a little bit more worried	2	7.1	0	0
My feelings have not changed	8	28.6	3	23.1
I feel a little less worried	10	35.7	6	46.2
I feel a lot less worried	8	28.6	4	30.8
N	28	100.0	13	100.0

4.5 Changes in Health-related Quality of Life

CHU9D scores at T1, T2 and T3 did not follow a normal distribution. This was assessed using visual inspection of histogram, and via the Shapiro-Wilk test.

As the data were not normally distributed, the Freidman test was used to assess changes between T1, T2, T3. One participant who returned T3 missed out four questions from the CHU9D, therefore their data was excluded from analysis.

The change in CHU9D scores between T1, T2, T3 using the Freidman test showed a statistically significant reduction in CHU9D score. However, there was also no statistically significant change between T1 to T2 assessed via Wilcoxen signed-rank test. This indicates a statistically significant reduction in HRQoL, which occurred between T2 to T3.

Table 9 Freidman test of changes in CHU9D between T1, T2, T3

Timepoint	N	25th Centile	Median	75th Centile
T1	14	12.00	15.00	19.25
T2	14	9.00	15.00	19.25
T3	14	9.00	11.00	16.25

p value 0.023

Table 10 Wilcoxon signed-rank between T1-T2

Timepoint	N	25th Centile	Median	75th Centile
T1	40	12.00	13.50	17.00
T2	28	10.00	14.00	19.00

p value 0.142

4.6 Free-text comments on the CBT guide

A section of the T1 and T2 questionnaires enabled free-text responses for comments about the green booklet 'Your Teeth, You Are In Control'. The free-text responses on T2 and T3 questionnaires were mainly left blank. Of the participants who responded, the majority had positive comments about the CBT guide and how it made them feel. One participant reported that they had lost the green book.

Table 11 Free-text comments on the CBT guide at T2

Free-text responses at T2
Not worried because I know what is going on
It makes me feel a bit better. I like having the agreement with the dentist. I will keep using the book when I come again.
It is a good book, useful information

That the green booklet will make my teeth a lot better by following the instructions.
I liked the booklet
It helps me understand a little more about the dentist

Table 12 Free-text comments on the CBT guide at T3

Free-text responses at T3
It was easy to understand and it helped me with my visits
It helped me to not feel as nervous
It helped me be less worried about going to the dentist and explained what to expect and also I could tell the dentist to stop if I needed to and that was OK to do. Thank you!
Lost green book

4.7 Analysis of Participant Dropout

4.7.1 Comparing T1 dental anxiety scores for those who completed T2 to those who did not

An independent t-test was used to compare T1 CEDAM interval scores for those who completed T2 and those who did not (dropouts before T2). No statistically significant difference in T1 dental CEDAM scores was identified. The mean anxiety at T1 was slightly higher for those who completed the study to T2, compared to dropouts who had slightly lower mean anxiety levels, but this was not statistically significant, with a p value of 0.74. This suggests that the reduction in dental anxiety identified after use of the intervention should not be attributed to attrition of more anxious patients.

Table 13 Independent t-test for CEDAM interval score at T1 for those who completed T2 and those who did not complete T2

Point of follow up	Mean T1 CEDAM score	Standard Deviation (SD)	Mean Difference
Completed T2	22.3	2.7	
Did not complete T2	20.7	3.1	-1.6

p value 0.74

4.7.2 Comparing T1 dental anxiety scores for those who completed T3 to those who did not

An independent t-test was also used to compare T1 CEDAM interval scores for those who completed T3 and those who did not (dropouts between T2 to T3). No statistically significant difference in T1 dental CEDAM scores was identified. Similar to the comparison of dropouts prior to T2, the mean anxiety at T1, those who dropped out between T2 to T3 had slightly lower mean anxiety levels than those completing the study, but this was not statistically significant, with a p value of 0.82. This comparison is reassuring and reduces the risk that attrition led to bias in the results.

Table 14 Independent t-test for CEDAM interval score at T1 for those who completed T3 and those who did not complete T3

Point of follow up	Mean T1 CEDAM score	Standard Deviation (SD)	Mean Difference
Completed T3	22.2	2.8	
Did not complete T3	21.6	2.8	-0.6

p value 0.82

4.7.3 Comparing demographics for those who followed up and those who did not complete study

Overall the participant demographics were similar for those who completed the study to T3, to those who did not (study dropouts) for age, ethnicity, index of multiple deprivation, and ASA grade. There were some differences between the groups for sex, and additional needs .

Mean age, and age range were the same between groups, with age skewed to the lower end of the range studied. There was slightly increased skew to the younger age in those who did not complete the study.

The percentage of female participants completing the study was greater than for males, with a higher percentage of males not completing the study to T3. Ethnicity was similar with the majority of participants being White British.

In the group who did not complete T3, 84.6 lived in the 50% most deprived dropouts, compared to 93.4% for those who completed the study. ASA grade was very similar between those who completed to T3 and those who did not with the majority ASA 1.

No patients with ADHD or autism completed the T3 questionnaire, whereas 23.1% of those who did not complete had additional needs. Detailed analysis of the data revealed the number of participants completing the T2 questionnaires, and the number completing their course of treatment was not different according to presence of ADHD or autism; it was the returning of the questionnaires at T3 which was incomplete.

Table 15 Demographics for those who completed and those who did not complete study

	Completed to T3		Did not complete to T3	
Variable	N	%	N	%
Age 8-12 years	9	60.0	21	80.8

13-15 years Mean age Age range	6 11years 8-16 years	40.0	5 11years 8-16 years	19.2
Sex				
Male	5	33.3	18	69.2
Female	9	60.0	8	30.8
Non-binary	1	6.7	0	0
Ethnicity				
White British	13	86.7	23	88.5
Other White Background	0	0.0	1	3.8
Asian Pakistani	1	6.7	2	7.7
Other Asian Background	1	6.7	0	0
Index of Multiple Deprivation (Decile)				
1 (most deprived)	4	26.7	8	30.8
2	4	26.7	3	11.5
3	1	6.7	3	11.5
4	3	20.0	4	15.4
5	2	13.3	4	15.4
6	0	0.0	0	0.0
7	0	0.0	1	3.8
8	0	0.0	2	7.7
9	1	6.7	1	3.8

10 (least deprived)	0	0.0	0	0.0
ASA Grade 1 2	 12 3	 80.0 20.0	 21 5	 80.8 19.2
Additional needs (ADHD, Autism)	0	0.0	6	23.1

Chapter 5 Discussion

5.1 Summary of key findings

The primary aims of this study were to assess whether dental anxiety was reduced following use of the self-help CBT guide during dental treatment and compare HRQoL before and after use. The findings indicate a highly statistically significant reduction in dental anxiety of -2.3 at T2 and -3.3 at T3 following use of the self-help CBT guide during a course of dental treatment. The difference is close to the suggested minimally important difference (MID) of -3.9, although this MID needs further investigation and may underestimate the effect of tools for managing dental anxiety [126]. The clinical significance of the reduction in dental anxiety is indicated by 64% feeling less worried about attending the dentist after using the guide at T2 and 77% at T3, after using it for the full course of treatment. Acceptance of LA during treatment is 61% which is similar to other forms of CBT delivery, such as psychologist-led and dentist-led [114, 115].

A statistically significant improvement in HRQoL is seen by the reduction in CHU9D scores after treatment from 15 at baseline to 11 at T3.

There were positive free-text comments on the self-help CBT guide, but some indicated barriers, such as losing the booklet.

The difficulties faced in recruitment to the study, and retention of participants were similar to findings from other studies [110]. The complexity of participants seen within the CDS was also relatively high, which may explain some of these barriers to recruitment and retention.

5.2 Interpretations and context

5.2.1 Changes in Dental Anxiety

Changes in CEDAM scores between T1, T2 and T3 indicate a positive reduction in dental anxiety of participants after using the self-help CBT guide for dental treatment. The paired t-test between T1-T2 has greatest power with 28 participants included. CEDAM levels reduce by -2.33 from 22.29 at baseline to 19.96 at T2. The repeated measures ANOVA indicates a further -1.08 reduction at T3, with total reduction of -3.32 for the 15 participants who returned the T3 questionnaire three months after treatment completion. This additional reduction between T2-T3 could be predicted, as the guide continued to be used during the

dental treatment after the T2 questionnaire, leading to further reduction in dental anxiety. The decision was made for T2 questionnaires to be completed after the patient's first treatment, rather than at the end of the full treatment course to reduce dropout through any subsequent WNB. This however means that the T2 scores may underestimate the effect of using the resource for a full course of treatment. Moving the timing of this measure to the end of the full course of treatment may have provided a more accurate representation of the reduction in dental anxiety. However patients failing to return for treatment, and those who had not completed their course, would have further reduced the power of the study.

The T3 timepoint, 3 months after completion of their course of treatment was chosen, as this was likely to be the time the participants return to their general dental practitioner. Within the CDS the majority of patients attend for a single course of treatment, and on completion, are discharged back to their GDP. As the majority of patients are referred due to caries, and are high caries risk, we recommend that they are reviewed by their GDP at 3 monthly intervals for fluoride varnish application until their caries risk reduces. This timepoint was, therefore designed to assess whether any changes to dental anxiety were maintained over time, and when attending a different dental clinic.

The further reduction in CEDAM scores between T2-T3 may be explained by the continued use of the guide throughout treatment after T2 embedding the coping strategies, and further reducing anxiety of the participants. This score also indicates that the reductions were maintained over the three months after treatment completion and discharge from the CDS. This may mean that coping strategies learnt, and the use of the guide made a lasting reduction in dental anxiety levels. It may however be that participants knew they had no current treatment needs. The wording of the CEDAM questionnaire should minimise this risk, as it asks questions about how the respondent would feel in specific scenarios. Another possible factor would be that dropouts at the T3 time point may have led to response bias with only those who had found the guide useful replying. Porritt et al, carried out a feasibility study looking at reduction in dental anxiety after using the same self-help CBT guide in a dental hospital setting [121]. They found a reduction in dental anxiety after the intervention. A follow up study indicated that this reduction was maintained 12-18 months after their treatment was complete [122]. Over 90% of respondents felt less worried about dental visits than prior to the intervention. Within this time over 80% had attended their GDP, with more than half having further dental treatment [122]. This supports the findings at T3 of a sustained reduction in DFA following the intervention.

The results of these studies cannot be directly compared due different measures being used for DFA. Porritt et al used the MCDAS which indicated a statistically significant large reduction in DFA after use of the guide [121]. Our findings from the CEDAM show a statistically significant reduction, but the clinical significance is difficult to determine due to the lack of definitive minimally important difference (MID) for the CEDAM.

Porritt et al hypothesise that -3.86 may be the MID for the CEDAM [126]. Our study found a difference of -3.32 at T3, which is slightly below this suggested MID, indicating that this may not be a clinically significant difference to the participant. However, the authors acknowledge that this MID was based upon a small sample size and needs further testing. They warn that reliance on this MID may underestimate the effect of anxiety measures tested using the CEDAM.

Participant responses to question 16 are indicative of a clinically significant difference to participants; with 64% participants feeling less worried since using the green booklet at T2 and 77% at T3. However, as this study had no control group receiving standard care, it cannot be ascertained whether the reduction in dental anxiety was due to use of the self-help CBT guide, or the behaviour management techniques of the staff. Comparing this to the study by Porritt et al, which recruited and treated participants within both Dental Hospital and CDS clinics, they found a greater effect on DFA, with 35% a little less worried and 60% a lot less worried, in comparison to 36% and 41% respectively in our study. Porritt et al found only 2% had feelings unchanged, compared to 23% in this study [121]. This indicates that there were a cohort of participants for whom use of the CBT guide did not change their feelings about attending the dentist. This fits with Porritt et al conclusions, that self-help CBT is not appropriate for all children with dental anxiety [121]. It also reflects other studies which found CBT effective in 70-73% of the study population [114, 115].

Question 15 suggests that at T2, 75% participants felt less worried about going to the dentist since their first visit to the CDS clinic, and 77% at T3. This indicates the need for a randomised controlled trial to assess the effect of the CBT guide, compared to standard behaviour management techniques. Some participants report being a little more worried about attending the dentist since their first visit to the CDS clinic, at T2 (10.7%) and after using the green booklet (7.1%). However, no participants felt more worried by T3. This may be due to further use of the guide, and behaviour management techniques from the staff

helping to reduce anxiety. Alternately it could have been that those who were more anxious did not continue in the study, introducing attrition bias as discussed in section 5.3.

The percentage of participants experiencing reduction in dental anxiety and accepting treatment with this self-help CBT guide is similar to the studies on psychologist-led and dentist-led CBT in which 64% and 70% accepted treatment respectively [113, 115]. This may suggest a similarity in effectiveness. Research would be beneficial to test this hypothesis, comparing the effectiveness of psychologist-led, dentist-led and self-help CBT with standard behaviour management techniques. If effectiveness is similar, the self-help technique may be a more cost-effective and time-efficient method of delivery.

Just over half the patients approached agreed to participate in the study. This is slightly lower than in the feasibility trial by Porritt et al for whom two-thirds agreed to participate [121]. They also had a much higher completion rate of 86%, compared to 37% to T3 and 68% to T2 for this study. This may be due to the limitations outlined in section 5.3.

The difficulties in recruitment to this study including the high rate of participants declining to participate, reflect the findings of Boman et al [110]. They also reported a high percentage of participants either declining to participate, or being ineligible. This needs to be considered in future research, with sample sizes taking these difficulties into account. The reasons for the recruitment and retention challenges are discussed further within the limitations section 5.3 (page 71).

5.2.2 Changes in Health Related Quality of Life

Results indicate a statistically significant change in HRQoL between baseline and at T3 from a median of 15 to 11. There was no change between T1-T2, which would be expected, as participants had not finished their dental treatment by this point. At T3 they had been discharged and were deemed dentally fit so the improvement in HRQoL at point this would then be expected. This reflects the findings of Porritt et al, who saw a statistically significant improvement in HRQoL after use of the CBT guide [121]. CHU9D was used as this measure was developed and validated with children [125]. Development involved extensive exploration of how health affects the lives of children via qualitative interviews with 74 children aged 7-11 years. The themes from the qualitative analysis guided the items on the questionnaire, indicating that the questions reflect the important aspects of a child's life in

relationship to their health. It covers the social, emotional and physical elements of a child's HRQoL. It is validated for use with children ages 7- 17-years old, covering the age of the study population. Use of the CHU9D measure worked well within the study. Children seemed to understand the questions well, with all questionnaires fully completed except one in which a page had been missed.

5.2.3 Free-text Comments

Positive responses were received in the free-text section of the questionnaire, although response rate to this question was low. Of those who completed the T2 questionnaire, 21% made free-text comments, and of the 15 participants who completed the T3 questionnaire 27% made comments.

The positive answers centre around a better understanding of what to expect at the dentist with comments such as "*Not worried because I know what is going on*", "*It helps me understand a little more about the dentist*", "*It helped me be less worried about going to the dentist and explained what to expect*". This reflects findings of the Porritt et al qualitative interviews with participants regarding their views of the self-help CBT guides [121]. The responses also share similarities with the qualitative exploration of psychologist-led CBT by Shahnavaz et al, and their themes of "autonomy and control" and "reduced fear" [113].

There were positive comments relating to a sense of control including "*I like having the agreement with the dentist*." "*I could tell the dentist to stop if I needed to and that was OK to do.*". There were also positive answers about using the book; "*It is a good book, useful information*", "*I liked the booklet*", "*It was easy to understand and it helped me with my visits*". This also mirrors the findings by Porritt et al, of "Control and choice" being valued by participants [121].

One comment related to loss of the green book, but did not state at which point during the dental treatment plan the book was lost; "Lost green book". This is similar to findings of barriers to engagement through qualitative interviews by Porritt et al [121], with reports of children failing to complete sections of the guide, or forgetting to bring the guide to appointments. This may suggest use of the digital online copy would be more beneficial for some patients, or indicate the benefit of alternative versions such as apps. It also supports the need for spare copies of the "Message to dentist" section to be available for patients to

complete in surgery if they forget their guide. Further research into different methods of delivery, such as via digital application may be beneficial. However, this should be considered with caution due to the risk of increasing digital exclusion. The Child of the North report discusses the "digital divide" which was highlighted during the COVID-19 pandemic [127]. Children from areas of deprivation were less likely to have access to digital platforms due to prohibitive costs of devices, internet connections and electricity. If digital access to self-help CBT interventions increases, it is important that non-digital versions continue to be available.

Further collection of rich qualitative data is indicated to explore more of the experiences of the participants using the resource in the CDS settings. Qualitative interviews with participants would facilitate this and is one of the recommendations set out below.

5.2.4 Demographics

The ethnicity of the sample population is similar but not entirely reflective of the population of Wakefield, with 87.8% of the study population White British compared to 79.8% within Wakefield population [128].

The majority of the study population live in areas with a high level of deprivation as measured by the Index of Multiple Deprivation, with 46% of the study population living within the 20% most deprived areas of England, and 88% within the 50% most deprived areas of England. This reflects the population of Wakefield, which is overall within the 10% most deprived areas of England [128]. This may have affected attendance and increased the attrition rate within the study due to difficulty accessing the clinics for appointments, costs of transport and parental time off work. West et al found that a higher proportion of children from the most deprived quintile (24.9%) were not brought to appointments than those from the least deprived (11.9%) [129]. The authors in this paper used data from primary dental care. We may anticipate the effects to be increased in specialist-led services such as the CDS, where often patients need to travel further to appointments. Chadwick et al investigated the indirect financial costs of parents bringing their child to medical appointments [130]. The mean cost was £35.36 with a major component being loss of income. They also found that 8% of parents had previously not brought their child to an appointment due to financial concerns. The findings were similar in a study of orthodontic secondary care which found that patients from an area of high deprivation had 2.7 times likelihood of not being brought to

appointments than those from affluent areas [131]. Location in particular has been stated as a barrier to attending dental visits in the Adult Dental Health Survey, however there is no data on this in the Child Dental Health Survey [132].

We recruited a greater number of younger children to the study than older, with 73% participants within the 8-12 age bracket. All eligible children between 8-16 years were invited to participate in the study, with the aim to achieve an even number within each age range. As discussed in section 1.4.2.3 some literature suggests that DFA is more prevalent in younger age groups [3, 24, 23, 26] which may explain the higher recruitment of younger participants. However due to conflicting literature including the UK CDHS suggesting higher prevalence in adolescents, this association is not definitive [25].

Males were better represented in this study than in previous literature, with a slightly higher percentage of males (56%) than females (42%) and one non-binary participant (2%). Many of the studies into management of DFA in both adult and child populations include a greater number of females, than males [98, 100, 101, 102, 106, 107, 108, 109, 113, 114, 115, 121]. This more equal gender balance in our study improves the generalisability of the results for use of self-help resources with male and female patients.

The main reason for treatment was dental caries, which is similar to the study by Porritt et al [121]. Fewer participants in this study had previous experience of GA or inhalational sedation, compared to Porritt et al [121]. This may be due to limitations in access to dental care in the previous years due to the COVID-19 pandemic. The number of decayed, missing or filled teeth per participant was more than 3 times greater than the average for 12-year-old children in Wakefield of 1.1, indicating that this cohort had a high level of dental need [128]. This would be expected within the secondary care service as referrals are only accepted for children meeting specific criteria for dental need. Within the sample population 20% were ASA 2, indicating a level of medical complexity. This fits with the average case mix score, which is a measure of the overall patient complexity. It covers ability to communicate, to co-operate, medical status, oral risk factors, patient access to oral care and any legal and ethical barriers to care with the scores fitting a range from standard patient to extreme complexity [133]. The complexity of participants ranged from some complexity to severe complexity, with the average being moderate complexity. This highlights that the CDS treat a complex cohort of patients, with dental anxiety often being part of a wider range of barriers to dental

care. This may explain some of the difficulties of recruitment and retention, with participants having additional barriers to attendance of appointments.

Of the participants completing the study, 61% accepted local anaesthesia (LA) during their treatment. This is a large increase on the 20% who had accepted LA prior to referral. This is similar to 64% LA acceptance rates after psychologist-led CBT found by Shahnavaz et al [114], and 70% LA acceptance for dentist-led CBT in children with intraoral injection phobia [115].

Fewer participants required inhalation sedation in this study compared to Porritt et al, with 37% participants having at least one component of their treatment under IHS compared to 79% respectively [121]. The percentage of participants requiring some of their treatment under GA was similar between studies, with 17% in our study compared to 13% for Porritt et al [121].

The was not brought (WNB) rate of participants during the study was comparable to the average cancellation rate for Wakefield CDS. WNB rate within the study population was 8%, whereas the overall WNB rate within the service varies between 5-10%. Cancellation rate was 4% for the study population, however this cannot be compared as the service does not calculate this figure. Evidence suggests that patients with DFA have a higher rate of cancellations and WNBs [37]. As levels of DFA are not routinely recorded for patients within the service, we do not know the rate of missed appointments for children in the service treated by standard behaviour management techniques. Future studies could calculate the cancellation and WNB rates for dentally anxious patients treated with standard behaviour management techniques. This would enable identification of any difference in missed appointments between the groups.

5.2.5 Participant Dropout

Comparison of the anxiety scores for participants at T1 between those who completed follow up and those who did not (study dropouts), indicated no statistically significant difference in anxiety score. This is reassuring and indicates a lower risk of attrition bias affecting the results. It indicates that the reduction in anxiety at T2 and T3 was not due to anxious participants failing to complete the study.

Looking at the demographics, a higher percentage of female participants completed the study, than male participants. This may indicate that the intervention is more acceptable to females, or may be that the male participants were less motivated to complete the follow up questionnaires. Differences in acceptability between male and female participants may be observed in more depth during the qualitative phase of the study.

There was a difference in the number of participants with additional needs (ADHD and/or autism) completing the study to T3. This makes the study results less generalisable to patients with additional needs. Further scrutiny of the data indicated a similar percentage of participants with additional needs completing T2, and that these participants completed their course of treatment. It was just the final T3 forms that were not returned via post. Children with additional needs were included in this study, as they frequently access dental care within the Community Dental Services. It is therefore important to include them in research, to ensure they can access evidence-based treatment options, relevant to their own needs. Further research would be valuable into the effectiveness and acceptability of this intervention with children with ADHD and autistic children.

5.3 Limitations and Barriers

Challenges were faced with recruitment within this study from the outset. Initially the protocol and ethical approvals were gained for Rotherham NHS Foundation Trust CDS. Barriers to commencing the study included restricted clinician time availability. Clinicians were asked to complete Good Clinical Practice training to enable them to recruit their own participants. However pressures on clinician's clinical time led to a long delay in completion of training, delaying the recruitment start date. Additionally pressure on time at new patient visits meant clinicians often did not have time to recruit participants. This led to the Principal Investigator booking eligible patients onto Saturday clinics and attending to carry out the consent and assent process in the waiting room prior to the new patient visit. This was a more successful method for recruiting participants as it did not impact upon clinician time.

The COVID-19 pandemic and changes to normal dental practice led to suspension of the study. The participants recruited at the original site of Rotherham NHS Foundation Trust could not complete the study as dental treatment was not carried out in the normal manner and face-to-face appointments were limited. The Principle Investigator and supervisor moved

to a new CDS, therefore the decision was made to add this as a site. A non-substantial amendment was made to the ethical approval, and capacity and capability were confirmed by the Mid Yorkshire NHS Hospitals Trust Research Department. Plans were made to improve recruitment by booking eligible patients into specific research new patients clinics. To avoid the barriers of limited clinician time and training, it was decided that consent would be carried out in the waiting room prior to the new patient appointment. Support was negotiated through the NIHR Clinical Research Network (CRN), as the study was adopted to the portfolio. This support included a Research Assistant from Mid Yorkshire Hospitals NHS Trust to assist with recruitment and consent for participants. Unfortunately this support was subsequently withdrawn due to Trust focus on COVID-19 research during surges in infection rates. Therefore, the PI and research supervisor carried out consent, assent and recruitment paperwork for all participants prior to their new patient appointments. Support from research assistants may have enabled a greater number of research clinics to be run than the Principle Investigator (PI) was able to run alone, and a greater number of eligible participants to be booked on each recruitment clinic. In future studies these barriers could be overcome by designing the recruitment process with support from research assistants ensuring an appropriate number of research trained staff are available to carry out consent and assent prior to appointments.

These barriers to recruitment led to the target of 75 participants not being met. This target had been chosen due to anticipated attrition rate of 40% over the three timepoints. Attrition rate to T3 was higher than anticipated, with only 37% recruited participants returning the T3 questionnaire. At T2 there was response from 68% recruited participants. The majority of the dropouts were due to failure to return the postal questionnaire at T3, with a smaller number who had not been brought for treatment, or who's treatment was not yet complete.

These barriers led to the sample size of 43 at T3 not being reached and the study therefore being underpowered. This increases the risk of a type 2 error through failure to identify a true difference. These difficulties in recruitment due to patients declining participation, or not meeting the inclusion criteria have been highlighted by Boman et al when recruiting to a randomised controlled trial [110]. Future studies should take this into account, by incorporating support for recruitment, and ensuring the recruitment takes into account the anticipated attrition rate.

The high dropout rate may also introduce attrition bias. There is the risk that the full course of treatment, and T2/T3 questionnaires were only completed by those who found the guide helpful. This puts the study at risk of a type 1 error, finding a difference where no true difference exists. There is also the risk of response bias, that participants may have responded in a way they felt the researchers wanted or expected them to respond. Future studies may need to explore novel methods for keeping participants engaged and reducing dropout.

There is a risk of selection bias, due to the percentage of participants agreeing to participate in the study. Just over half the patients approached agreed to participate in the study. There is a risk that only participants who felt that the self-help CBT approach would work for them agreed to take part. This however, supports the evidence that CBT is not suitable for everyone, and needs to be considered within a range of other DFA management options.

The generalisability of the study may be limited within different setting and different patient groups. The majority of recruited participants were White British, therefore the results may not be representative for other ethnicities. Further research is needed within different patient groups and settings. In further studies stratified sampling could be undertaken to include participants from a range of backgrounds.

As there was no control group in this study we cannot determine whether the changes in DFA or HRQoL were due to the self-help CBT intervention, to treatment in secondary care setting with professionals experienced in treating children, or a combination of both. Treatment by experienced professional teams is therefore a confounding factor in the study. Ideally we would have included a control group receiving standard behaviour management techniques, to assess any differences in CEDAM and CHU9D changes between groups. This was not feasible within this study due to time and funding constraints, but would be beneficial in future research. This would also enable investigation of any differences in the number of participants needing pharmacological treatment for their dental treatment between groups. Use of pharmacological methods was also a confounding factor for those who engaged in treatment under IHS and/or GA.

An additional confounding factor is the information about the CBT study which patients received prior to their new patient visit. Knowing that they would receive support and management of their dental anxiety may have reduced their levels of DFA at the new patient visit, leading to artificially low CEDAM scores at T1. This could have been prevented by asking the patient to complete the T1 questionnaire prior to the study information. This

however would have been unethical, as patients would then be completing a research questionnaire before they consented to inclusion in the study. It would also have given them only a very short time to read and assimilate the information about the study before consenting. It was therefore deemed more appropriate to send the information in advance, to provide adequate time for patient and parent understanding, and to achieve fully informed consent. This effect may be reduced in a randomised controlled trial where participants are unaware of which type of management they will receive when they are completing the initial questionnaire. Comparison of the participants' T1 CEDAM scores with the scores of children with DFA in other studies may indicate whether any reduction took place prior to completion of T1. However, the CEDAM is a relatively new tool, so there are a no DFA prevalence scores in the literature for children with DFA. The CEDAM was used as it is based upon the theoretical framework of the Five Areas cognitive behavioural model of anxiety, therefore investigates all aspects of dental anxiety. It has high reliability, and was developed with involvement of children, reflecting outcomes that they deem important. Use of a different dental anxiety measure such as the CFSS-DS or the MCDAS may have enabled comparison between DFA at baseline, and overall prevalence of DFA in the literature. However, as discussed in the literature review these measures would not have assessed unhelpful thoughts, behaviours, or physical reactions. They also had limited involvement of children in their development, potentially making them less relevant to the aspects which children find important than the CEDAM.

This study fulfilled its aim of assessing use of the self-help CBT guide service-wide within a community dental service, but may be less generalisable to other settings. The results may be useful for other CDS with a similar skill-mix considering utilising the CBT self-help guides, but may be less generalisable to general dental practice where professionals have different skills, less time and fewer specialist resources for treating anxious patients. As professionals in general dental practice have fewer specialist skills in treating anxious children, it can be hypothesised that the resource may be have greater benefit in GDP settings. This is currently being investigated by a randomised controlled trial which is looking at the effectiveness of the resource in GDP settings [134]. Outside the UK system, other countries have different professional skill mix and practice set-ups. The results may be useful in these other settings, as the guide has been translated into several languages, but the different populations, professional settings, and structure of care in different countries means further research in those specific settings would be valuable.

Chapter 6 Conclusions and Recommendations

The findings indicate a reduction in dental anxiety after use of the self-help CBT resource within a CDS setting. This supports use of the resource within other CDS settings. However, qualitative exploration of patients and clinician feelings about the resource used in this setting would be valuable including the barriers and facilitators to its use.

The reduction in dental anxiety cannot be attributed to use of the self-help CBT guide due to the limitations of the study design. Therefore a randomised controlled trial is indicated to compare use of the self-help CBT guide to standard behaviour management techniques. It would be valuable to include a health economics component to evaluate cost differences between arms. This could include evaluation of the need for additional pharmacological methods for managing DFA, and the costs associated with this. This would tie in with a sustainability measure. Pharmacological methods of anxiety management can have negative environmental impacts. In particular the use of nitrous oxide can increase the carbon emissions of an individual procedure by a magnitude of ten times [135]. Investigating whether use of self-help CBT reduces the need for sedation using nitrous oxide may help clinicians and patients make sustainable decisions about delivery of healthcare.

Future research into self-help CBT, and research within the CDS, needs to anticipate and account for recruitment and retention challenges. This may include using additional measures to facilitate recruitment such as additional recruitment support to avoid impacting on clinician time, or compensation to the service for time spent recruiting. The acceptance rate of just over 50% for patients agreeing to participate in the study should be considered in future studies, with a recruitment timescale that takes this into account.

Although this study indicated a quantitative reduction in dental anxiety within participants, further rich information should be gathered through qualitative exploration of the barriers and facilitators to its use. Qualitative interviews with participants and clinicians after use of the CBT guide is recommended.

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Appendices

Appendix A Research Ethics Committee favourable opinion letter

NHS
Health Research Authority

London - Queen Square Research Ethics Committee
HRA NRES Centre Manchester
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8019

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

25 February 2019

Miss Susan Welford
Paediatric Dentistry Department, University of Leeds,
The Worsley Building
Clarendon Way, Leeds
LS2 9LU

Dear Miss Welford

Study title:	**Does the use of self-help Cognitive Behavioural Therapy (CBT) resources reduce dental anxiety in children aged 8-16 years, referred to Rotherham NHS Foundation Trust Community Dental Services?**
REC reference:	**19/LO/0303**
IRAS project ID:	**252388**

The Proportionate Review Sub-committee of the London - Queen Square Research Ethics Committee reviewed the above application on 13 February 2019.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

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

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Extract of the meeting minutes

Social or scientific value; scientific design and conduct of the study

The Sub Committee asked whether the home visit was necessary.

The Sub Committee also asked could the research not be performed only at the clinic.

The research team responded by informing the Sub Committee that the home visits was considered to be a necessary option for participants, as it was the opinion of the team that some of the participants would have felt more comfortable talking about their dental anxiety in the comfort of their own home. It would also allow them to achieve more variation within the sample, by interviewing at home those participants who would otherwise find it difficult to attend the clinic purely for an interview.

The Sub Committee were satisfied with the response.

Informed consent process and the adequacy and completeness of participant information

The Sub-Committee noted that the research team had provided age-appropriate information sheets (e.g. 8-12) which were very good. They stated the need for assent forms to match the information sheets.

The research team provided an age appropriate assent form.

The Sub Committee reviewed this and was happy with the assent form provided.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Leeds Indemnity]		17 September 2018
Interview schedules or topic guides for participants [Topic Guide Participants]	1	18 March 2018
Interview schedules or topic guides for participants [Topic Guide Dental Professionals]	1	18 March 2018
IRAS Application Form [IRAS_Form_29012019]		29 January 2019
Letter from sponsor [Confirmation of Sponsorship]		18 December 2018
Letter from statistician [Comments from statistician]		08 October 2018
Letters of invitation to participant [Letter of Invitation]	1	05 December 2018
Other [Participant Data Recording Sheet]	1	15 March 2018
Other [Cognitive Behavioural Therapy Resource]		
Other [Cognitive Behavioural Therapy Parent Advice Sheet]		
Other [App U Phase 1 questionnaire 8-12 yrs assent form copy]	1	22 February 2019
Participant consent form [Phase 1 Parent/Carer Consent Form]	1	15 March 2018
Participant consent form [Phase 1 Participant Assent Form]	1	15 March 2018
Participant consent form [Phase 2 Parent/Carer Consent Form]	1	15 March 2018
Participant consent form [Phase 2 Participant assent Form]	1	15 March 2018
Participant consent form [Phase 2 Dental Professional consent Form]	1	23 October 2018
Participant information sheet (PIS) [Participant information sheet 8-12 years]	1	15 March 2018
Participant information sheet (PIS) [Participant information sheet 13-16 years]	1	15 March 2018
Participant information sheet (PIS) [Parent/Carer Information Sheet]	1	15 March 2018

Participant information sheet (PIS) [Dental Professional Information Sheet]	1	23 October 2018
Referee's report or other scientific critique report [Critique of Research by Educational Supervisor]		12 October 2018
Research protocol or project proposal [Protocol]	1	05 December 2018
Sample diary card/patient card [Qualitative diary]	1	19 August 2018
Summary CV for Chief Investigator (CI) [CV]		14 October 2018
Summary CV for student [Postgraduate student CV]		15 December 2018
Summary CV for supervisor (student research) [Educational Supervisor CV]		14 October 2018
Summary CV for supervisor (student research) [CV Zoe Marshman]		
Summary CV for supervisor (student research) [Research CV Rachael Nichol]		01 June 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Chart]	1	15 March 2018
Validated questionnaire [App C T1 Validated Questionnaire CEDAM and CHU9D]		
Validated questionnaire [App D T2 Validated Questionnaire CEDAM and CHU9D]		
Validated questionnaire [App E T3 Validated Questionnaire CEDAM and CHU9D]		

Membership of the Proportionate Review Sub-Committee

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

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

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

19/LO/0303	**Please quote this number on all correspondence**

Yours sincerely

PP: Dr Eamonn Walsh
Chair

Email: nrescommittee.london-queensquare@nhs.net

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

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Faculty NHS Research Ethics Officer*
Ferzanah Salim, Rotherham NHS Foundation Trust Professor Bernadette Drummond

Appendix B Health Research Association Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Miss Susan Welford
Paediatric Dentistry Department, University of Leeds,
The Worsley Building
Clarendon Way, Leeds
LS2 9LU

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

28 February 2019

Dear Miss Welford

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Does the use of self-help Cognitive Behavioural Therapy (CBT) resources reduce dental anxiety in children aged 8-16 years, referred to Rotherham NHS Foundation Trust Community Dental Services?**
IRAS project ID:	**252388**
REC reference:	**19/LO/0303**
Sponsor	**University of Leeds**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

IRAS project ID	252388

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Tel: 0113 343 7587
Email: governance-ethics@leeds.ac.uk

IRAS project ID	252388

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **252388**. Please quote this on all correspondence.

Yours sincerely

Kevin Ahmed
Assessor

Telephone: 0207 104 8171
Email: hra.approval@nhs.net

IRAS project ID	252388

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. The sponsor is not requesting, and does not require any additional contracts with study sites.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	Study funding will be provided to sites, as detailed at Schedule 1 of the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments

IRAS project ID	252388

Section	Assessment Criteria	Compliant with Standards	Comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

All sites will undertake the same research activities therefore there is only one site type.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

IRAS project ID	252388

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator should be appointed at study sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
As a non-commercial undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix C Confirmation of Capacity and Capability Rotherham NHS Foundation Trust

RFT Ref: 19-01-03 confirmation of C&C Use of a CBT resource for children with dental anxiety

SALIM, Ferzanah (THE ROTHERHAM NHS FOUNDATION TRUST)

Tue 09/04/2019 12:41

To: WELFORD, Susan (LEEDS TEACHING HOSPITALS NHS TRUST) <susan.welford@nhs.net>;

Cc: governance-ethics@leeds.ac.uk <governance-ethics@leeds.ac.uk>; NICHOL, Rachael (THE ROTHERHAM NHS FOUNDATION TRUST) <rachael.nichol@nhs.net>; CURTIS, Katy (THE ROTHERHAM NHS FOUNDATION TRUST) <katy.curtis@nhs.net>; B.K.Drummond@leeds.ac.uk <B.K.Drummond@leeds.ac.uk>; COLLINS, Philippa (THE ROTHERHAM NHS FOUNDATION TRUST) <philippa.collins1@nhs.net>; BULL, Nisha (THE ROTHERHAM NHS FOUNDATION TRUST) <nisha.bull@nhs.net>; z.marshman@sheffield.ac.uk <z.marshman@sheffield.ac.uk>;

Dear Susan,

RFT Ref	19-01-03
IRAS Number:	252388
REC Ref:	19/LO/0303
REC Approval date:	7th February 2019
HRA Approval date:	28th February 2019
Study title	Does the use of self-help Cognitive Behavioural Therapy (CBT) resources reduce dental anxiety in children aged 8-16 years, referred to Rotherham NHS Foundation Trust Community Dental Services?
Chief Investigator:	Professor Bernadette Drummond
Sponsor:	University of Leeds

The Research Department has received the required documentation as listed below:

1. -	**Evidence of local Capacity and Capability**	
	Clinical Director	Nisha Bull 08/04/2019
	Data Protection Officer	Derek Stowe 11/03/2019
	Finance Manager	Greg Wright 22/03/2019

Please find confirmation of capacity and capability for your academic research study which is being sponsored by University of Leeds. You may now begin your research. Study documents to be used are those versions listed on the REC/HRA approval letter.

Appendix D Amendment for addition of new site

IRAS 252388. Amendment

New IRAS Dev <no-reply-iras@hra.nhs.uk>
Thu 7/29/2021 17:22
To: WELFORD, Susan (LEEDS TEACHING HOSPITALS NHS TRUST) <susan.welford@nhs.net>

IRAS Project ID: 252388
Sponsor amendment reference: Amendment 1

Thank you for submitting your study amendment. In accordance with the outcome of your completed amendment tool, this amendment requires no further regulatory review. Please now share this amendment with your UK research sites, in accordance with the instructions in your completed amendment tool.

For studies with more than one UK research site, your amendment will now be automatically shared with the R&D offices of any NHS/HSC research sites in Scotland and Northern Ireland, but you should share the amendment by email directly with those Research team/s.

For all NHS research sites in England and Wales, please now share this amendment by email directly with those sites, including both the R&D offices and research teams.

Do not reply to this email as this is an unmonitored address and replies to this email cannot be responded to or read.

Appendix E Participant information sheet 8-12 years

UNIVERSITY OF LEEDS

NHS
The Mid Yorkshire Hospitals
NHS Trust

Helping young people feel better about going to the dentist

Participant 8-12 years Information Sheet

We would like to invite you to take part in our research study. Before you decide whether to take part or not we would like to explain to you why the research is being done and what it would involve for you.

One of our team will go through this information sheet with you, and answer any questions you have. You can also talk to other people about this research if you wish to.

Thank you for reading this.

1. What is research?

Research is a careful experiment to find out the answer to an important question

2. Why is this project being done?

Many children and young people feel worried about visits to the dentist. We want to find ways of helping young people feel less worried about visits to the dentist.

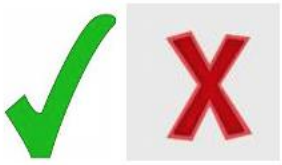
3. Why me?

We have invited you to take part because your dentist has mentioned that you may be worried or afraid about visits to the dentist. We want to talk to about 75 children and young people who feel the same way.

4. Do I have to take part?

No, it's up to you to decide, and it's your choice. If you choose not to take part it will not affect any treatment or care you have in the future.

If you do choose to take part you will first sign a form to say you agree. You can still change your mind at any time, and you don't need to explain your reason for this.



5. What will happen?

The research study will involve you filling in a questionnaire and a guide that is to help young people who are worried about visiting a dentist. The dentist who sees you will help you with the guide. You will then be asked to fill in the questionnaire again after treatment. The questionnaire will be sent out in the post for you to complete again after 3 months.

20 children will also be invited to fill in a diary about the guide and interviewed to find out what they thought about the guide. If we ask to interview you, you can choose whether you would like to be interviewed or not. You can also choose where it takes place: either at the dental clinic or at your home. The interview can last as long as you wish, but normally lasts about 30 minutes. We will record the interview so that we can remember what you say, but your answers will be private, and we will not use your name on anything in the study. But, if you tell us something important, and we think we can help you with it, then a dentist looking after you will contact you and your parents or carers to talk through things and arrange for you to get the right help.

We will be able to give you a gift voucher for £10 as a thank you for taking part.

6. What else might happen?

There are no risks to you or your parents or carers from taking part in the study. We do know that talking and thinking about something you are worried or afraid about can be difficult for some young people, but you don't have to talk about anything you don't want to.

The study will not change the treatment or care you receive at the dentist. Completing the guide may help you become less worried about going to the dentist. We also hope that it will help other young people in the future.

7. What happens when the research study stops?

You will have your dental visits as normal. You may still use the guide if you wish to.

8. What if something goes wrong?

Your mum, dad or carer will be able to talk to someone who will be able to tell them what they need to do about it.

9. What if I don't want to do the research anymore?

Just tell your mum, dad, carer or dentist at any time. They will not be cross with you. You will still have the same care.

10. What if I wish to complain about the study?

If you want to complain you or your mum, dad or carer can talk to Susan Welford or Rachael Nichol at this dental clinic, or on the telephone 01302 563163.

11. Will anyone else know I'm doing this?

No-one apart from our research team will know that you took part. We won't use your name or address on anything. We will write down the interviews without using your name, then we delete the recordings.

12. What happens to what the researchers find out?

When we collect your information we will make sure it is stored in a safe place and only the people doing the research study can look at it.

We will use the information to teach dentists how to help children who are worried about going to the dentist, and we will put it in medical magazines for other dentists to read. We will not use your names on anything so no-one will know you were in the study.

We will let all the young people who took part in the project know what we found out

13. Did anyone else check the study is OK to do?

This study has been checked by lots of people, to make sure it is alright.

14. How can I find out more about this study?

Your mum, dad, carer or other grownup you trust may be able to answer your questions. The dentists and dental nurses looking after you can also help you find out more about the study.

Thank you for taking the time to read this – please ask any questions if you would like

Appendix F Participant information sheet 13-16 years

UNIVERSITY OF LEEDS

NHS
The Mid Yorkshire Hospitals
NHS Trust

Helping young people feel better about going to the dentist

Participant Information Sheet

We would like to invite you to take part in our research study. Before you decide whether to take part or not we would like to explain to you why the research is being done and what it would involve for you.

One of our team will go through this information sheet with you, and answer any questions you have. You can also talk to other people about this research if you wish to.

Thank you for reading this.

What is the purpose of the study?
Many children and young people feel anxious or afraid about visits to the dentist. The overall aim of the research is to assess ways of helping young people overcome their fears about visits to the dentist.

Why have I been invited?
We have invited you to take part in this study because your dentist has mentioned that you may be anxious or afraid about visits to the dentist. We want to talk to about 75 children and young people in total who feel the same way.

Do I have to take part?
No, it's up to you to decide, and it's your choice. If you choose not to take part it will not affect any treatment or care you have in the future.

What will I have to do if I do agree to take part?
If you do choose to take part you will first need to sign a form to say you agree. You can still change your mind at any time, and you don't need to explain your reason for this.

The research study will involve you completing a questionnaire and a guide that is to help young people who are anxious about visiting a dentist. The dentist who sees you will help provide support with the guide. You will then be asked to complete the questionnaire again after your treatment. The questionnaire will be sent out in the post for you to complete a third time after 3 months.

20 children will be invited to fill in a diary about the guide and be interviewed to find out what they thought about the guide. If we ask to interview you, you can choose whether you would like to be interviewed or not. You can also choose where the interview takes place: either at the dental clinic or at your home. The interview can last as long as you wish, but on average will last about 30 minutes. We will record the interview so that we can remember what you say, but your answers will be private, and we will not use your name on anything in the study. We may use quotes when we publish our research, but we would not use your name or anything to identify you, so no one will know that it was you. However, if you tell us something important, and we think we can help you with it, then a dentist looking after you will contact you and your parents or carers to talk through things and arrange for you to get the right help.

We will be able to give you a gift voucher for £10 as a thank you for taking part.

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What are the possible benefits of taking part?
The study will not change the treatment or care you receive at the dentist. Completing the guide may help you manage your fears and anxieties about going to the dentist. We also hope that it will help other young people in the future.

What are the possible disadvantages or risks of taking part?
There are no risks to you or your parents or carers from taking part in the study. We do know that talking and thinking about something you are anxious or afraid about can be difficult for some young people, but you don't have to talk about anything you don't want to.

What happens when the research stops?
You will have your dental visits as normal. You may still use the guide if you wish to. You will be able to keep your guide and diary if you like, but we will keep a copy too.
At the end of our research we keep these documents very securely for 5 years, but they won't have your name on.

What is there is a problem or something goes wrong?
If you or your parents or carers become unhappy about how you have been looked after in the study, your concerns will be taken seriously.

If you have a concern about this study, then please feel free to contact:
Professor Drummond, Chief Investigator for the research study.
Telephone number: 01302 563163

If you are still unhappy and want to make a complaint, you can do this by writing to:
Rachael Nichol, Consultant in Paediatric Dentistry
Wakefield Community Dental Clinic, Newstead House, 11 Bond Street, Wakefield, WF1 2QP

Will anyone else know I've taken part in the study?
No-one apart from our research team will know that you took part. We won't use your name or address on anything. All the information from the study will be kept securely at the University of Leeds. The interview recordings will be transcribed and anonymised then the recordings deleted as soon as possible.
You can find out more about how we use your information by contacting: DPO@leeds.ac.uk

How will your data be managed?
The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
Mid Yorkshire NHS Trust will collect information from you for this research study in accordance with our instructions.

Mid Yorkshire Hospitals NHS Trust will keep your name, NHS number and contact details confidential and will not pass this information to the University of Leeds. Mid Yorkshire Hospitals NHS Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the University of Leeds and regulatory organisations may look at your research records

to check the accuracy of the research study. The people who analyse the information will not know your name, NHS number or contact details.
Mid Yorkshire Hospitals NHS Trust will keep identifiable information about you from this study for 3 months after the study has finished. Anonymised research data will be stored securely for 5 years.
When the interviews are transcribed we may use an external company, but a confidentiality agreement will be in place and a unique identifier will be used.
The questionnaires, guides and diaries will use a unique identifier and so will not contain any personal information. These will be stored in a locked secure room within Leeds School of Dentistry.
We may use quotes when we publish our research, however these would not have any identifying information and would be completely anonymous.
When you agree to take part in a research study, the anonymous information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.
This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how we use your information by contacting:
DPO@leeds.ac.uk

What will happen to the results of the research study?
The results will be presented at a Paediatric Dentistry Conference and published in scientific journal, but your answers will be confidential and we will not use your names on anything. We will let all the young people who took part in the project know what we found out.

Who is organising and funding the research?
The study is being organised by Susan Welford, Professor Zoe Marshman, Consultant Mrs Rachael Nichol and Professor Bernadette Drummond from the Schools of Dentistry at the University of Leeds and University of Sheffield. Funding to support this study will come from the University of Leeds.

Who has checked the research study?
All the research in the NHS Is looked at by an independent group of people, called a Research Ethics Committee. Their role is to look after your interests. This study was checked by London - Queen Square Research Ethics Committee.

Contact details
If you want to know more or you have a question about the research study, please feel free to contact me:

Susan Welford
Telephone number: 01302 563163
Or by writing to Leeds School of Dentistry, Clarendon Way, Leeds LS2 9LU

Appendix G Parent/Carer information sheet

UNIVERSITY OF LEEDS

NHS
The Mid Yorkshire Hospitals
NHS Trust

Helping young people feel better about going to the dentist

Parent/Carer Information Sheet

We would like to invite you and your child to take part in our research study. Before you decide whether to take part or not we would like to explain to you why the research is being done and what it would involve for you both.

One of our team will go through this information sheet with you and answer any questions you have. You can also talk to other people about this research if you wish to.

Thank you for reading this.

What is the purpose of the study?
Many children and young people feel anxious or afraid about visits to the dentist. The overall aim of the research is to assess ways of helping young people overcome their fears about visits to the dentist.

Why have I been invited?
We have invited you and your child to take part in this study because your dentist has mentioned that your child may be anxious or afraid about visits to the dentist. We want to talk to about 75 children and young people in total who feel the same way.

Do I have to take part?
No, it's up to you and your child to decide, and it's your choice together. If you choose not to take part it will not affect any treatment your child will have in the future.

What will my child and I have to do if we do agree to take part?
If you and your child choose to take part you will first need to sign a consent form to say you agree, and your child will sign an assent form to say that they agree to take part. You can still change your mind at any time, and you don't need to explain your reason for this.

The research study will involve your child completing 2 questionnaires asking how they feel about going to the dentist, and a guide that is to help young people who are anxious about visiting a dentist. The dentist who sees you and your child will help provide support with the guide throughout the course of treatment to try to help your child cope with, and overcome their dental anxiety. Your child can use this guide between visits to help them manage their dental anxiety. They can spend as much or as little time using the guide as they wish. Your child will then be asked to complete the questionnaires again after their first treatment. The questionnaire will be sent out in the post for your child to complete a third time after 3 months.

An additional 20 children will be invited to fill in a diary about the guide before and after their dental visits, and be interviewed after all their treatment is complete, to find out what they thought about the guide. You can choose where the interview takes place: either at the dental clinic or at your home. The interview can last as long as your child wishes, but on average will last about 30 minutes. We will record the interview so that we can remember what your child says, but your answers will be private, and we will not use either of your names on anything in the study. However, if your child tells us something important, and we think we can help them with it, then a dentist looking after your child will contact you and your child to talk through things and arrange for your child to get the right help.

We will be able to give your child a gift voucher of £10 as a thank you for taking part.

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NHS Trust

What are the possible benefits of taking part?
The study will not change the treatment or care your child receives at the dentist. Completing the workbook may help your child manage their fears and anxieties about going to the dentist. We also hope that it will help other young people in the future.

What are the possible disadvantages or risks of taking part?
There are no risks to you or your child from taking part in the study. We do know that talking about something you are anxious or afraid about can be difficult, but you and your child don't have to talk about anything you don't want to.

What happens when the research stops?
Your child will have their dental visits as normal. They may still use their workbook if they wish to.

What is there is a problem or something goes wrong?
If you become unhappy about how you, or your child, have been looked after in the study, your concerns will be taken seriously.

If you have a concern about this study, then please feel free to contact:
Professor Drummond, Chief Investigator for the research study.
Telephone number: 01302 563163

If you are still unhappy and want to make a complaint, you can do this by writing to:
Rachael Nichol, Consultant in Paediatric Dentistry
Wakefield Community Dental Clinic, Newstead House, 11 Bond Street, Wakefield, WF1 2QP

Will anyone else know I've taken part in the study?
No-one apart from our research team will know that you or your child took part. We won't use your child's name or address on anything. All the information from the study will be kept securely at the University of Leeds. The interview recordings will be transcribed and anonymised then the recordings deleted as soon as feasible.

What will happen to the results of the research study?
The results will be presented at a Paediatric Dentistry Conference and published in scientific journal, but your answers will be confidential and we will not use your names on anything. We will let all the young people and parents and carers who took part in the project know what we found out.

How will your data be managed?
The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you and your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

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NHS
The Mid Yorkshire Hospitals
NHS Trust

Mid Yorkshire Hospitals Trust will collect information from you and your child for this research study in accordance with our instructions.

Mid Yorkshire Hospitals Trust will keep your name, NHS number and contact details confidential and will not pass this information to the University of Leeds. Mid Yorkshire Hospitals Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the University of Leeds and regulatory organisations may look at your research records to check the accuracy of the research study. The people who analyse the information will not know your name, NHS number or contact details.
Mid Yorkshire Hospitals Trust will keep identifiable information about you from this study for 3 months after the study has finished. Anonymised research data will be stored securely for 5 years.
When the interviews are transcribed we may use an external company, but a confidentiality agreement will be in place and a unique identifier will be used.
The questionnaires, guides and diaries will use a unique identifier and so will not contain any personal information. These will be stored in a locked secure room within Leeds School of Dentistry.
We may use quotes when we publish our research, however these would not have any identifying information and would be completely anonymous.
When you agree to take part in a research study, the anonymous information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.
This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how we use your information by contacting:
DPO@leeds.ac.uk

Who is organising and funding the research?
The study is being organised by Susan Welford, Professor Zoe Marshman, Consultant Mrs Rachael Nichol and Professor Bernadette Drummond from the Schools of Dentistry at the University of Leeds and University of Sheffield. Funding to support this study will come from the University of Leeds.

Who has checked the research study?
All the research in the NHS Is looked at by an independent group of people, called a Research Ethics Committee. Their role is to look after your interests. This study was checked by London - Queen Square Research Ethics Committee.

Contact details
If you want to know more or you have a question about the research study, please feel free to contact me:
Susan Welford
Telephone number: 01302 563163
Or by writing to Leeds School of Dentistry, Clarendon Way, Leeds LS2 9LU

Appendix H Participant Assent form

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NHS
The Mid Yorkshire Hospitals
NHS Trust

Participant Identification Number:

Name of young person involved in the study:

Helping young people feel better about going to the dentist

Participant Assent Form **Please initial all boxes**

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information given, ask any questions, and have had these answered satisfactorily. ☐
2. I understand that it is completely up to me whether I want to be involved in the study. I can change my mind and not be in the study any more, without having to explain my reasons, and without my rights being affected. ☐
3. I understand that I will be filling in questionnaires, and I understand the reasons for this. ☐
4. I understand that the questionnaires and what I say will only be used for research purposes. This will include research publications. I understand that my name will not be used, so no-one apart from the research team will know what I said. ☐
5. I agree to other doctors or dentists who look after me being informed that I am in the study if it will help me. ☐
6. I agree to participate in the study ☐

Name of young person	Date	Signature
Name of person taking assent	Date	Signature

Chief Investigator: Professor Drummond Telephone number: 01302 563163

1 copy given to participant, 1 copy kept in research file, 1 copy into patient notes

Appendix I Parent/Carer Consent Form

Use of a CBT resource for children with dental anxiety/Parent or Carer consent form/phase 1
Version 3 26/06/2021/IRAS252388

UNIVERSITY OF LEEDS

NHS
The Mid Yorkshire Hospitals
NHS Trust

Participant Identification Number:
Name of young person involved in the study:

Helping young people feel better about going to the dentist

Parent/Carer Consent Form **Please initial all boxes**

1. I confirm that I have parental responsibility for the above person. ☐
2. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider all the information given, ask questions, and have had these answered satisfactorily. ☐
3. I understand that my participation and my child's participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my child's dental care or legal rights being affected. ☐
4. I understand that questionnaires will be filled in and analysed. I have had an explanation of, and understand the purpose for which these will be used. ☐
5. I understand that any information obtained will be used for research purposes only. This will include research publications. Anonymity and confidentially will be preserved at all times. ☐
6. I agree to other medical professionals being informed of my child's participation in the study if it is identified during the course of the study that it is in my child's best interests. ☐
7. I agree for my child to participate in this study. ☐

Name of parent or carer	Date	Signature
Name of person taking consent	Date	Signature

Chief Investigator: Professor Drummond Contact number: 01302 563163

1 copy given to parent, 1 copy kept in research file, 1 copy into patient notes

Appendix J CEDAM and CHU9D Questionnaire

Use of a CBT resource for children with dental anxiety/T1 Questionnaire/phase 1
IRAS252388

T1
Participant number:
Date:

Questionnaire about going to the dentist and how you feel

Hello

Thanks for agreeing to complete the questionnaire. In this booklet, you will find some sets of questions about you, how you feel about going to the dentist, and how you feel about yourself.

We would be very grateful if you could answer all the questions using the instructions, then give it back to the dentist or lady at the desk.

There are no right or wrong answers.

Section 1 About you

1. Are you: (please tick)

A boy ..... ☐
A girl ..... ☐

2. How old are you? .....years

Please ask your parent or carer if you need help with this

Section 2 Going to the dentist

Instructions

For each question please read all the choices and decide which one is most like you today.

The questions have no right or wrong answers.

When I know I have an appointment with the dentist	
(please tick one box)	
☐	I will do nothing to avoid going
☐	I will do some things to avoid going
☐	I will do everything to avoid going

When I know I have an appointment with the dentist	
(please tick one box)	
☐	I will tell my parents I don't mind going
☐	I will tell my parents I would rather not go
☐	I will tell my parents I really don't want to go

When I next visit the dentist	
(please tick one box)	
☐	I will let the dentist look in my mouth
☐	I will try to stop the dentist looking in my mouth a bit
☐	I will not let the dentist look in my mouth

When I next visit the dentist	
(please tick one box)	
☐	I will not get worried if the dentist tells me I need to have something done
☐	I will get a little worried if the dentist tells me I need to have something done
☐	I will get really worried if the dentist tells me I need to have something done

When I next visit the dentist	
(please tick one box)	
☐	If I asked the dentist to stop what they were doing they would definitely stop
☐	If I asked the dentist to stop what they were doing they might stop
☐	If I asked the dentist to stop what they were doing they would not stop

When I next visit the dentist I think	
(please tick one box)	
☐	I will not be worried that it will be painful
☐	I will be a little worried that it will be painful
☐	I will be very worried that it will be painful

When I next visit the dentist I think	
(please tick one box)	
☐	Nothing will go wrong
☐	Something will go a bit wrong
☐	Something will go very wrong

When I next visit the dentist I think	
(please tick one box)	
☐	I will have a lot of control over what happens in the appointment
☐	I will have a bit of control over what happens in the appointment
☐	I will not have any control over what happens in the appointment

When I next visit the dentist I think I will	
(please tick one box)	
☐	Not feel shaky
☐	Feel a little shaky
☐	Feel very shaky

When I next visit the dentist I think I will	
(please tick one box)	
☐	Not feel stressed
☐	Feel a little stressed
☐	Feel very stressed

When I next visit the dentist I think I will	
(please tick one box)	
☐	Not feel upset
☐	Feel a little upset
☐	Feel very upset

When I next visit the dentist I think I will	
(please tick one box)	
☐	Not feel embarrassed
☐	Feel a little embarrassed
☐	Feel very embarrassed

When I next visit the dentist I think I will	
(please tick one box)	
☐	Not feel angry
☐	Feel a little angry
☐	Feel very angry

When I next visit the dentist I think I will	
(please tick one box)	
☐	Feel that I can completely trust the dentist
☐	Feel that I can only trust the dentist a bit
☐	Feel that I can't trust the dentist

Section 3 How do you feel?

These questions ask about how you are generally **today.** They are not about going to the dentist. For each question, read all the choices and decide which one is most like you **today**. Then put a tick in the box next to it. Only tick **one** box for each question.

1. Worried	
☐	I don't feel worried today
☐	I feel a little bit worried today
☐	I feel a bit worried today
☐	I feel quite worried today
☐	I feel very worried today

2. Sad	
☐	I don't feel sad today
☐	I feel a little bit sad today
☐	I feel a bit sad today
☐	I feel quite sad today
☐	I feel very sad today

3. Pain	
☐	I don't have any pain today
☐	I have a little bit of pain today
☐	I have a bit of pain today
☐	I have quite a lot of pain today
☐	I have a lot of pain today

4. Tired	
☐	I don't feel tired today
☐	I feel a little bit tired today
☐	I feel a bit tired today
☐	I feel quite tired today
☐	I feel very tired today

5. Annoyed	
☐	I don't feel annoyed today
☐	I feel a little bit annoyed today
☐	I feel a bit annoyed today
☐	I feel quite annoyed today
☐	I feel very annoyed today

6. School work/homework (such as reading, writing, doing lessons)	
☐	I have no problems with my schoolwork/homework today
☐	I have a few problems with my schoolwork/homework today
☐	I have some problems with my schoolwork/homework today
☐	I have many problems with my schoolwork/homework today
☐	I can't do my schoolwork/homework today

7. Sleep	
☐	Last night I had no problems sleeping
☐	Last night I had a few problems sleeping
☐	Last night I had some problems sleeping
☐	Last night I had many problems sleeping
☐	Last night I couldn't sleep at all

8. Daily routine (things like eating, having a bath/shower, getting dressed)	
☐	I have no problems with my daily routine today
☐	I have a few problems with my daily routine today
☐	I have some problems with my daily routine today
☐	I have many problems with my daily routine today
☐	I can't do my daily routine today

9. Able to join in activities (things like playing out with your friends, doing sports, joining in things)	
☐	I can join in with any activities today
☐	I can join in with most activities today
☐	I can join in with some activities today
☐	I can join in with a few activities today
☐	I can join in with no activities today

[Type here]

Section 4

Last question! We would like to know whether the way young people think about going to the dentist is affected by their background. Please tick the box that best describes your ethnic group, you only need to tick **one** box on this page. Ask your parent or carer to help you with this section if you need to.

A: White

- ☐ English/Welsh/Scottish/Northern Irish/British
- ☐ Irish
- ☐ Gypsy or Traveller
- ☐ Any other White background, write in

B: Mixed/multiple ethnic groups

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other Mixed/multiple ethnic background, write in

C: Asian/Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Chinese
- ☐ Any other Asian Background, write in

D: Black/African/Caribbean/Black British

- ☐ African
- ☐ Caribbean
- ☐ Any other Black/African/Caribbean background, write in

E: Other ethnic group

- ☐ Arab
- ☐ Any other ethnic group, write in

Finally, please let us know whether you would be willing for us to contact you again about this project? Yes ☐ No ☐

Thank you very much for your help

Appendix K Excerpts from guided self-help CBT intervention

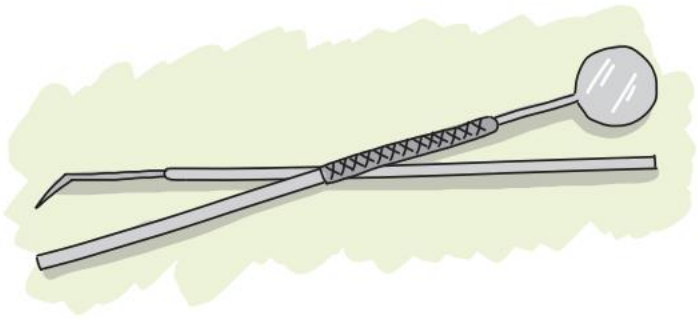
Sometimes we can have bad thoughts about visiting the dentist which make our anxiety worse. These might include...

Help! Going to the dentist will really kill.

They won't listen to me, they don't know what it's like to be a young person at the dentists.

I won't be able to handle it.

I'll embarrass myself.



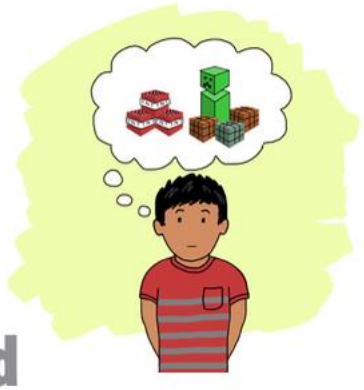
Having a check-up

If your family has a car it probably has a service every year. It keeps everything running properly, and prevents problems building up. It's the same with teeth- regular checks once a year make a lot of sense. During the check-up the dentist will count your teeth (they like maths), check they are growing in the right place and look for signs of tooth decay.

During the check-up the dentist will use:

- a mirror
- a pointer to remove bits of food - crisps always get stuck between your teeth!
- a spray of air over your teeth to dry them

These are all things which they do to make sure they can check your teeth and mouth thoroughly.

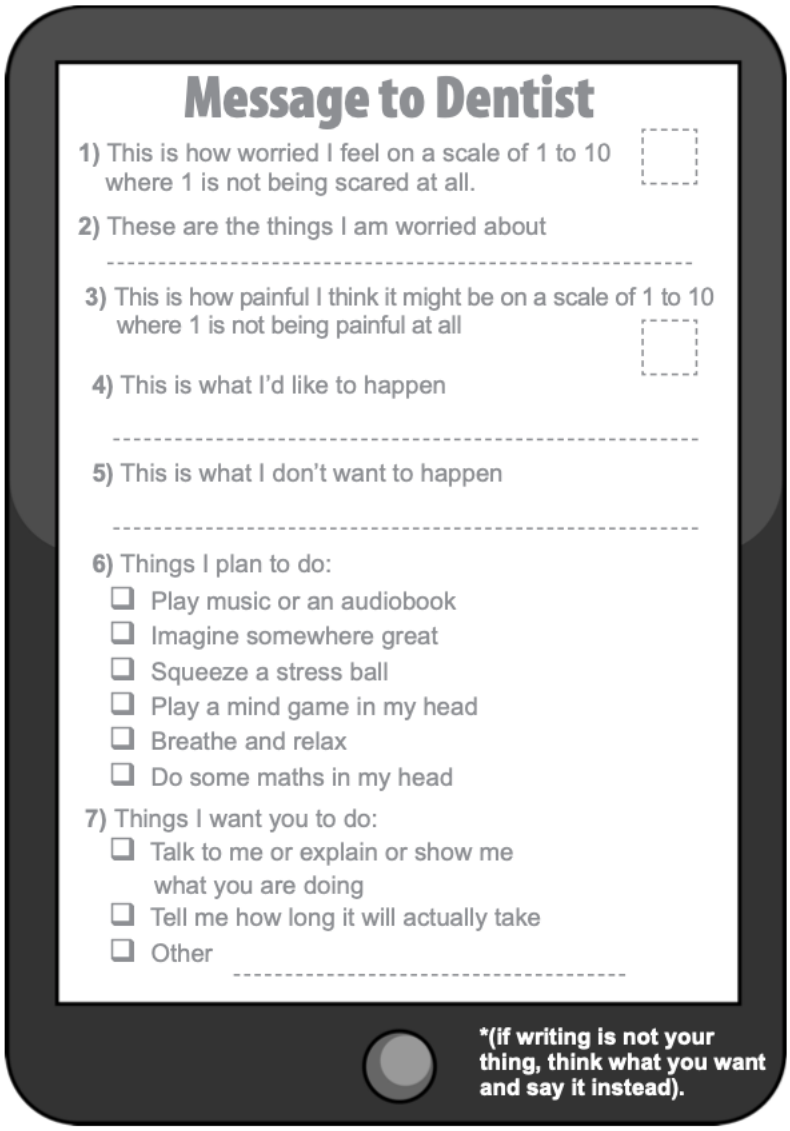


1. Focus your mind

You've got a choice when you're waiting or sitting in the dental chair. You can choose to listen to the bad thought, or not.

Here are some simple things you can focus on to drown out the bad thought:

- Play a mind game: Why not bring a game or phone along to use in the waiting room. Then when you're in the chair continue to play the game in your head. Rotate those blocks, dig those tunnels, defend that tower – whatever you're into try it and enjoy – no apps needed.
- Love or hate maths? – now's time for some practice. Anyone know their 13 times table?


Message to Dentist
1) This is how worried I feel on a scale of 1 to 10 where 1 is not being scared at all.
2) These are the things I am worried about
3) This is how painful I think it might be on a scale of 1 to 10 where 1 is not being painful at all
4) This is what I'd like to happen
5) This is what I don't want to happen
6) Things I plan to do:
Play music or an audiobook
Imagine somewhere great
Squeeze a stress ball
Play a mind game in my head
Breathe and relax
Do some maths in my head
7) Things I want you to do:
Talk to me or explain or show me what you are doing
Tell me how long it will actually take
Other
*(if writing is not your thing, think what you want and say it instead).

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