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Article

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Development and testing of a Cognitive Behavioural Therapy resource for children's dental anxiety

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Statement of knowledge transfer

This study details the development of a guided self-help Cognitive Behavioural Therapy resource for the management of children's dental anxiety and provides preliminary evidence for the feasibility and acceptability of this approach with children aged between 9 and 16 years. The results of this study will inform the design of a definitive trial to examine the treatment and cost-effectiveness of the resource for the reduction of children's dental anxiety.

Abstract

Background: Cognitive Behavioural Therapy (CBT) is an evidence-based treatment for dental anxiety; however, access to therapy is limited. The current study aimed to develop a self-help CBT resource for the reduction of dental anxiety in children and assess the feasibility of conducting a trial to evaluate the treatment and cost effectiveness of this intervention.
Method: A mixed methods design was employed. Within phase 1 a qualitative 'Person-based' approach informed the development of the self-help CBT resource. Guidelines for the development and evaluation of complex interventions were also used. Within phase 2 children, aged between 9-16 years, who had elevated self-reported dental anxiety and were attending a community dental service or dental hospital were invited to use the CBT resource. Children completed questionnaires, which assessed their dental anxiety and health-related quality of life (HRQoL), prior to and following their use of the resource. Recruitment and completion rates were also recorded. Acceptability of the CBT resource was explored using interviews and focus groups with children, parents/carers and dental professionals. The Mixed Methods Appraisal Tool criteria were adhered to.
Results: 24 families and 25 dental professionals participated in the development and qualitative evaluation of the CBT resource for dentally anxious children. A total of 56 agreed to trial the CBT resource (66% response rate) and 48 of these children completed the study (86% completion rate). There was a significant reduction in dental anxiety (mean score difference=7.7, t=7.9, *df*=45, p<0.001, Cohen's d ES=1.2) and increase in HRQoL following use of the CBT resource (mean score difference=-0.03, t=2.14, *df*=46, p<0.05, Cohen's d ES=0.3). The self-help approach had high levels of acceptability to stakeholders.
Conclusions: Findings provide preliminary evidence for the effectiveness and acceptability of the resource for the reduction of children's dental anxiety and support further evaluation of this approach in a randomised control trial.

Introduction

Dental anxiety commonly develops in childhood and over a third of children report some fear of visiting the dentist (Taani et al. 2005). Dental fear can prevent children from regularly engaging with dental services and completing dental treatment, which can negatively impact on the oral health status and quality of life of these children (Nicolas et al. 2010; Taani 2002; Townend et al. 2000). Dental anxiety often continues into adulthood with anxious children more likely to become symptomatic, rather than proactive, users of dental services when adults (Poulton et al. 2001).

Treating dentally anxious patients can be time consuming, challenging and can place financial demands on dental practices and services (Moore and Brodsgaard 2001). Anxious children are therefore one of the key groups that dental practitioners refer to specialist services for pharmacological interventions (e.g. sedation, general anesthetic) (Harris et al. 2008). Referrals to specialist services often result in patients having to travel further to access dental care and also cause longer delays in receiving dental treatment. Anxious patients can become dependent on pharmacological approaches to the management of their care particularly if they do not receive treatment for their anxiety (McGoldrick et al. 2001). Therefore, there is the potential for significant long-term benefits if early access to psychological interventions is available to reduce dental anxiety.

Meta-analyses have demonstrated Cognitive Behavioural Therapy (CBT) is often effective in treating a range of anxiety disorders in children (James et al. 2015) and a series of systematic reviews have demonstrated the effectiveness of CBT for the reduction of dental anxiety (Armfield and Heaton 2013; Gordon et al. 2013). The approach incorporates cognitive and behavioural techniques to modify unhelpful thoughts and behaviours that contribute to the maintenance of anxiety. Whilst there is evidence to support the use of CBT in the treatment of anxiety access to this therapy is often limited (Chavira et al. 2004; Merikangas et al. 2011). 'Pure self-help' (where an individual works through an intervention unsupported) and 'guided self-help' CBT (where a healthcare practitioner supports the individual to work through an intervention) provide alternatives to traditional therapist-led CBT therapy and can be used as part of a 'stepped care' approach to treatment (Bower and Gilbody 2005). The Five Areas model™ of CBT (Williams and Garland 2002), which focuses on the patient's life situation, altered thinking, altered behaviour, altered emotions and altered physical symptoms associated with their anxiety, offers an accessible model of assessment and management of dental anxiety that can be applied in clinical settings. This model has been used to theoretically inform a series of self-help resources for patients with a variety of common mental health problems (Williams 2012).

When developing an intervention it is important that the preferences and needs of users are examined in order to maximise the relevance and acceptability of the intervention (Yardley et al. 2015). Therefore, the aim of this study was to involve children, parents/carers and dental team members in the development of a CBT self-help resource for the reduction of children's dental anxiety and to investigate the feasibility of evaluating the effectiveness of this resource in a randomised control trial. The research was undertaken in two phases and the specific research objectives for each phase of the research were to:

Study phase 1:

- Develop a child-centred guided self-help CBT resource plus guidance notes for parents/carers and a training package for practitioners

Study phase 2:

- Collect data on recruitment, retention and completion rates for the CBT resource
- Examine effect size changes and variability in children's dental anxiety and quality of life following the use of the CBT self-help approach to determine the required sample size for a future trial
- Explore acceptability of the CBT resource to children, parents/carers and dental team members

- Determine whether preliminary evidence from the feasibility study supports continuation to a large scale randomised control trial

Study phase 1: Development of the CBT resource

Methods and Materials

The design of this research was informed by guidance for developing and evaluating complex interventions and the study consisted of a development phase and feasibility study (Craig et al. 2008). The EQUATOR Network research review guidance ('Mixed Methods Appraisal Tool'(Pace et al. 2012) and 'RATS' checklist (Clark 2003)('Relevance of study question', 'Appropriateness of qualitative method', 'Transparency of procedures' and 'Soundness of interpretative research') were adhered to. Ethical approval for the research was granted by the NRES Committee York and Humber: Leeds West REC (13/YH/0163). Informed written assent/consent was obtained from children, parents/carers and professionals and anonymity of data was explained to participants.

Design

The development of the self-help CBT resource was guided by the Five Areas model of CBT (Williams and Garland 2002), which focuses on enhancing the coping skills of individuals with anxiety using a mixture of cognitive and behavioural techniques. The 'Person-based' approach (Yardley et al. 2015) was employed to complement the theory-driven approach. This approach focuses on understanding and accommodating the perspectives and needs of people who will use an intervention and thus involves undertaking iterative in-depth qualitative research with stakeholders throughout intervention development (Yardley et al. 2015). Dentally anxious children, parents/carers and dental professionals were therefore all involved in the development of the CBT self-help resource. Dyadic interviews with children and parents/carers were undertaken and interviews/focus groups were undertaken with dental team members. Dyadic interviews and focus groups have the advantage that comments from one participant (e.g. parent) can encourage responses from the other participant (e.g. child) allowing for the stimulation of ideas (Morgan et al. 2013).

Children's personal experiences of dental anxiety (e.g. their thoughts, behaviours, physical symptoms, feelings and situational triggers of their dental anxiety) were explored during the interviews to ensure a young person-centred CBT resource was developed (Morgan et al. 2016). During these interviews participants were asked what they thought should be included in the CBT self-help resource (e.g. what they thought would help reduce their dental anxiety) and were asked to provide feedback on different format and delivery options (e.g. pure self-help versus guided self-help). Participants were shown draft versions of the resource and iterative modifications were made based on the feedback provided. Data collection and analysis were conducted concurrently until data saturation occurred and no new themes emerged. Interviews were audio recorded and transcribed verbatim.

The design of the self-help resource was led by a commissioned design company, utilising professional writers and designers.

Participants

As described previously young people aged 11 to 16 years with dental anxiety and their parents/carers were purposively sampled to provide a range of views (Morgan et al. 2016). The criteria used for sampling included: gender; age; dental setting (primary/secondary care) deprivation; and ethnicity. Children were approached by the researcher following the diagnosis of dental anxiety by the patient's dental clinician based on clinical judgment and experience. The researcher confirmed the presence of dental anxiety with participants. Participants were recruited from two general dental practices, the community dental service and a NHS paediatric dentistry unit, located within the South Yorkshire region of the UK. The age range was selected to recruit child participants of sufficient cognitive development to provide a detailed account of

their previous anxiety experiences using the specified CBT framework (James et al. 2015). A sampling matrix was used to monitor the recruitment of participants. Children with severe communication difficulties or who did not speak English were excluded. Of the 17 children who were approached, 13 children (N=10 female) aged between 11 and 15 years old and their parents/carers agreed to participate in this phase of the study.

A purposive sample of dental team members were also recruited from a diverse range of settings (e.g. primary dental care practices, community dental services and dental hospital), as outlined within the study protocol (Marshman et al. 2016). Nineteen dental team members (N=13 GDPs, N=2 paediatric dentists, N=2 dental nurses, N=1 community dentist, N=1 dental therapist) participated.

Materials
The topic resource for the interviews with children and parents/carers was based on the Five Areas CBT model (Williams and Garland 2002) developed by one of the researchers (CW) and included questions on past experiences of dental anxiety (e.g. to identify unhelpful thoughts, feelings, behaviours, physical symptoms and situational/contextual factors that need to be addressed within the CBT self-help resource). The topic resource for dental team members included questions about their previous experiences of managing dental anxiety (e.g. to identify practitioners' needs). Topic resources also examined stakeholders' preferences for the content, format and delivery of the resources.

Analysis
Framework analysis (using the Five Areas CBT model) was used to analyse the qualitative data generated from interviews with children and parents/carers. This is a pragmatic approach to qualitative research that draws on both inductive and deductive processes (Ritchie and Spencer 1994). Framework analysis involves the following stages: i) familiarisation with the data, ii) coding and identifying an analytic framework, iii) indexing (applying the analytic framework), iv) charting, and v) mapping and interpretation. The data generated from interviews with dental team members were analysed using thematic analysis and a hybrid approach of inductive and deductive coding and theme development was employed (Braun and Clarke 2006). An essentialist approach, which aims to report the experiences of participants, guided data analysis (Braun and Clarke 2006). Data was entered into Excel spreadsheets and two researchers were involved in the analysis of qualitative data to promote rigor of analysis (e.g. reliability of coding). Each researcher independently read and reviewed the transcripts to identify important and repeating ideas that emerged from the data. Any disagreements in interpretation were resolved through discussion.

Results and summary

Four themes were identified from the stakeholder interviews which specifically related to the development of the CBT resource, which included: 'pure versus guided self-help', 'supporting everyone involved', 'facilitators: engaging, informative and accessible' and 'potential barriers'. Details of how these data informed the development of the CBT resources are provided in Table 1. Table 2 details how the Five Areas model of CBT also guided the development of the CBT resources.

The results from the qualitative interviews with children enabled the content of the child resource to be developed and included sections about: i) how common dental anxiety is (in order to normalise children's feeling of anxiety), ii) the common 'unhelpful thoughts' that children with dental anxiety experience (using data provided by children in qualitative interviews), iii) how unhelpful thoughts can be challenged, iv) procedural and treatment information and v) cognitive and behavioural techniques/activities children can use when at the dental clinic.

Children expressed a preference for the resource to be made available in a mixture of formats (paper-based and online). The resultant resource entitled 'Your teeth. You are in control' has been produced as an A5 booklet and is also available online free of charge at www.llttf.com/dental.

Parents/carers and dental team members felt they would value information which would help *them* understand the child's dental anxiety better and provide practical tips of how they could help the child feel less anxious. As a result, complementary resources for parents/carers and dental team members were developed which included a resource for parents/carers and a dental team practice resource. These supporting resources were made available as A5 booklets, summary sheets and can also be accessed on-line from www.llttf.com/dental. A clinical protocol and communication script were also developed to support the practitioners' implementation of the guided CBT approach.

Children and other stakeholders advised against developing resources which included too much information and which would take too long to work through. Therefore various drafts of the resources were shown to children, parents/carers and dental team members to ensure the most important and relevant information was included in the resource, was written concisely and that sections could be completed quickly and while in the dental appointment, if required.

Study Phase 2: Feasibility study

Methods and Materials

Following the development of the CBT self-help resource a feasibility study was undertaken to determine whether further evaluation of the resource was warranted and possible. This phase of the study utilised a mixed method approach. A protocol providing detailed methodology related to the feasibility study has been published previously (Marshman et al. 2016). Informed written assent and consent was obtained from children and parents/carers/professionals, respectively, prior to their involvement in the research and anonymity of data was explained to participants.

Design and intervention

Two Community Dental Clinics, in Derbyshire, and one Dental Hospital, in the South Yorkshire region of the UK, recruited patients. New patients who presented at these clinics were given a 'screening slip' at reception asking them to indicate whether they were worried about going to the dentist. Patients who met all of the inclusion criteria and their parents/carers were invited to participate at this initial new patient visit.

At the next visit children and parents/carers who had indicated they did want to participate in the study were provided with the CBT self-help resource. The resource was explained to children and parents/carers/carers and children were asked to read the CBT self-help resource and complete the relevant sections (e.g. their 'message to the dentist') prior to their next appointment. Baseline dental anxiety and quality of life questionnaires were also completed by the child at this visit (T1). During their next two treatment appointments the clinician worked through and discussed specific sections of the CBT self-help resource with the patients and delivered the required dental treatments (e.g. fissures sealants, extractions, restorations). At the end of their third appointment patients completed the follow-up dental anxiety and quality of life questionnaires (T2). Further appointments (if required) were scheduled in accordance with patients' clinical needs.

Participants
To participate in this phase of the study children had to meet the following inclusion criteria: aged between 9-16, English speaking, respond 'a little bit worried' or 'very worried' to the screening question 'please tell us how you feel about going to the dentist', require a course of dental treatment which would involve at least three separate visits and not have an acute dental problem which requires urgent dental treatment. Lancaster and colleagues (Lancaster et al. 2004) recommend a minimum sample size of 30 to estimate a parameter such as a standard deviation (which is required to inform the sample size calculation for a future trial). Four paediatric dentists, two dental nurses and one dental therapist based in a community dental service and a paediatric dental hospital were involved in the delivery of the guided CBT self-help approach.

Materials
A clinical protocol and communication script was developed to support the practitioners' implementation of the guided CBT approach. Dental anxiety was assessed using the 8-item Modified Child Dental Anxiety Scale (MCDAS)(Humphris et al. 1998) which assesses children's concerns in relation to specific dental procedures (examination, scale and polish, injection, filling, extraction, inhalation sedation and general anaesthesia) and how the child feels generally when they visit the dentist. A 5-point Likert scale is used and total scores range from 8 (little or no dental anxiety) to 40 (extreme dental anxiety) and the measure has demonstrated good internal consistency (Cronbach alpha coefficient=0.84) (Humphris et al. 1998). Two global change questions were employed to assess self-reported change in dental anxiety (e.g. 'Has how you feel about going to the dentist changed since your first visit to the dental hospital?' and 'Has how you feel about going to the dentist changed since you started using the green booklet?'). A 5-point Likert response scale was used (1='I feel a lot less worried' to 5='I feel a lot more worried').

Health related quality of life (HRQoL) was assessed using the Child Health Utility 9D (CHU-9D) questionnaire (Stevens 2010). Children were asked to rate how they felt that day and nine domains were assessed (worried, sad, pain, tired, annoyed, school work/homework, sleep, daily routine, able to join in activities). Each domain has five response options and utility weights were calculated from the individual's responses. The UK tariff generates utility weights between .33 and 1 (perfect health), with a higher utility reflecting higher HRQoL. The CHU-9D has demonstrated an acceptable level of internal consistency (Cronbach alpha coefficient=0.78) (Furber and Segal 2015).

Analysis
Descriptive data on recruitment, retention/completion rates is presented. Wilcoxon signed ranks test were undertaken to analyse differences in individual items on the MCDAS that assess anxiety related to specific dental procedures (e.g. tooth extraction, inhalation sedation, injection and filling). Paired t-tests were used to compare baseline and follow-up total MCDAS scores and CHU-9D utility scores. Effect sizes were calculated using Cohen's d Effect Size (ES) statistic. To calculate total anxiety and utility scores for cases who had missing data, median scores for the specific MCDAS/CHU-9D items were imputed for cases where there was less than 50% of data missing from the total scale. Participants' responses to the global change questions are also reported.

Acceptability of the CBT resource
Qualitative research was employed because this is particularly useful for exploring issues concerning acceptability, implementation and practicality of an intervention and for exploring possible mechanisms of change (O'Cathain et al. 2015).

Design
Interviews were undertaken with children and parents/carers once children had completed the intervention. Children were given the option to be interviewed with their parent or separately. Interviews with dental professionals were also undertaken to examine their perspectives and experiences of using of the CBT self-

help resource. Data collection and analysis were conducted concurrently until data saturation occurred and no new ideas emerged. Interviews were audio recorded and transcribed verbatim.

Participants
A purposive sample of children who had taken part in the feasibility study (e.g. range of ages, gender, deprivation, engagement with resource) were invited to participate, with their parents/carers, to obtain a diverse range of experiences and perspectives. Twelve families were approached and 11 families participated in this phase of the research (one family declined due to other commitments). The characteristics of the participants are detailed in Table 3. Children were aged between 10 and 15 years old, the majority were female (N=7, 64%). Eleven mothers and two fathers participated.

Dental professionals' perspectives and acceptability of the CBT approach were explored using interviews/focus groups. Dental team members who were involved in the development of a CBT self-help resource were asked about their perceived acceptability of a CBT-resource for the management of dental anxiety within the initial series of interview/focus groups. Additional interviews were conducted with dental professionals who had used the CBT self-help book with patients.

Materials
The topic resource for children was based on the Five Areas CBT model (Williams and Garland 2002) and explored changes in children's experiences of dental anxiety as a result of the CBT intervention. It also covered children's and parents'/carers' views about the usefulness of the resource (acceptability) and the barriers associated with the use of the CBT self-help approach (usability). The topic resource for dental health team members was guided by the Theory of Planned Behaviour (Ajzen 1991) and explored factors that could influence practitioners' future use of the CBT self-help approach and its acceptability.

Analysis
Framework analysis was used and a hybrid approach of inductive (data-driven) and deductive (theory-driven) coding and theme development was employed (Ritchie and Spencer 1994). After coding the first three transcripts the two researchers involved compared the codes they had applied and agreed on a set of codes to apply to all subsequent transcripts. Coding and indexing was done manually and an Excel spreadsheet was used to chart data. Initial themes were discussed with the research team and reflexive engagement with the data contributed to the development of the final themes. Any disagreements in interpretation were resolved through discussion.

Results

Recruitment and completion rates
A total of 85 children were invited to participate in the feasibility study and trial the CBT resource. The recruitment rate (proportion of children invited to take part in the study who agreed to participate) and completion rate (proportion of children who agreed to participate who completed the study) was 66% and 86%, respectively (see Figure 1). A total of 48 patients completed the study. Table 4 provides a summary of the sample's characteristics, deprivation levels, treatment needs and engagement levels with the CBT resource.

Dental anxiety and Quality of Life
In response to the question to children 'Has how you feel about going to the dentist changed since your first visit to the dental hospital?' 35 (73%) participants indicated they felt 'A lot less worried' and 12 (25%) participants indicated they felt 'A little less worried' (missing data for 1 participant). In response to the question 'Has how you feel about going to the dentist changed since you started using the green booklet?' 29 (60%) participants indicated they felt 'A lot less worried', 17(35%) indicated they felt 'A little less worried' and 1 participant (2%) indicated their feelings had not changed (missing data for 1 participant).

The mean MCDAS score at baseline was 25.0 (SD=6.5, range=15 to 35) and at follow-up the mean score was 17.4 (SD=6.1, range=8 to 31). The results revealed a significant large reduction in dental anxiety following the CBT intervention (t=7.9, df=45, p<0.001, 95%CI=5.7 to 9.6, Cohen's d ES=1.2) (Cohen, 1992).

Wilcoxon signed ranks tests also revealed significant reductions in anxiety levels related to the following procedures: 'injection' (baseline median 5 'very worried', follow-up median=3 'fairly worried', z=-4.86, p<0.01); 'filling' (baseline median=4 'worried a lot', follow-up median=2 'very slightly worried', z=-4.04, p<0.01) 'tooth taken out' (baseline median=5 'very worried', follow-up median=3 'fairly worried', z=-4.51, p<0.01) and 'mixture of gas and air' (baseline median=3 'fairly worried', follow-up median=1 'relaxed/not worried, z=-3.15, p<0.01).

The mean CHU-9D utility score at baseline was 0.875 (SD=0.09, range= 0.51 to 1.0) and at follow-up the mean score was 0.904 (SD=0.08, range=0.68 to 1.0). The results revealed a significant *small* improvement in quality of life following the CBT intervention (t=-2.14, *df*=46, *p*<0.05, 95%CI= -0.06 to -0.00, Cohen's d ES=-0.3) (Cohen 1992). The proportion of children who reported HRQoL impacts decreased between baseline and follow-up for the following domains: worry (81% to 56%, respectively), sadness (23% to 19%, respectively), annoyed (17% to 8%, respectively), tired (73% to 56%, respectively), schoolwork (31% to 19%, respectively), sleep (27% to 25%, respectively), daily routine (21% to 10%, respectively) and joining in activities (38% to 19%, respectively). However, the proportion of children who reported impacts on HRQoL increased between baseline and follow-up for the pain domain (17% to 27%, respectively).

Children's and parents/carers' acceptability of the guided CBT self-help resource

Framework analysis revealed three themes and six subthemes within the data, which are discussed below. The coding templates and analytic framework used to develop the final themes are included in 'Additional file 1'.

Theme 1. 'A positive experience'

Children and parents/carers indicated that they were pleased that they had been offered the CBT resource and felt it had been useful in helping them/ their child manage their anxiety.

'An increased understanding'

Children particularly valued the information which was provided within the child CBT self-help resource (e.g. procedural information), which had increased the predictability of treatment and reduced their anxiety.

> *'I felt a little better when I knew what was happening and what the injections were'* (Participant group 4, male 14yrs).

'Less anxiety, more confidence'

Children indicated that they felt reduced levels of anxiety and worry following their use of the resource. Many of their worries and fears (e.g. 'I can't trust the dentist' and 'it will be painful') had been challenged as a result of them being able to obtain new positive experiences and feeling confident enough to talk through their concerns with their dentists. Children and parents/carers discussed how using the resource had made them feel more confident so they could cope when they visit the dentist.

> *'He was really scared of going. Then with the help of the lady dentist and the resource, he was happy to go. The last time it was "You don't have to go if you don't want to go" "Yeah I'm going. I'm going". So big difference'* (Participant group 1, mother).

However, some children felt they would still experience some anxiety in the future, for example, if they had to receive dental treatment without sedation.

'*Additional benefits*'
Many parents/carers felt the CBT resource had helped them understand their child's anxiety better and become more supportive when their child was anxious. Some parents/carers also reported reductions in their own dental anxiety as a result of supporting their child in using the CBT resource.

> *'I didn't realise how much it would help me*' (Participant group 1, mother).

Theme 2. 'Barriers to engagement'
Children found the child CBT self-help resource easy to follow and understand. However, children commonly reported that they had forgotten to complete sections of the resource prior to their appointment and to take the resource with them to the dentist indicating a potential barrier to engagement. Some children talked about how they would like to use the resource in the future, however, there was some uncertainty from children and parents/carers about how a general dentist would react to the guided self-help approach and this was cited as a reason why they might not use the resource in the future:

> *'I'm not saying they were bad or anything [general dentist] but they just don't always have the time. I don't know because it would probably help [using the resource]. It would probably speed things up*' (Participant group 11, mother).

While parents/carers thought having separate supporting parent guidance was useful, few had actually read the parent guidance due to a lack of time. Parents/carers did, however, help children read through the child CBT resource and this appeared to be useful for both children and parents/carers.

'Overcoming barriers'
Children and parents/carers appreciated the guidance that dentists had provided which had helped them work through key sections of the CBT resource. This 'guided' approach was seen as central to the building of positive patient-dentist relationships. Children and parents/carers also recognised the value of dentists having worksheets available for occasions when children had not remembered to take their CBT resource to their appointment.

Theme 3. 'The importance of communication and positive relationships'
'Communication and care'
A consistent finding was that the CBT resource helped children and parents/carers communicate with their dentist and develop a positive patient-dentist relationship. They viewed the action of their dentist giving them the child the CBT self-help resource as a sign that the dentist was interested in finding out about their dental anxiety and that they wanted to help them. Children felt that using the resource had enabled them to ask their dentist more questions than they normally would have and to talk about their anxiety more openly with the dentist.

> *'The message to the dentist'* (Participant group 5, Female 13yrs) *'You like that bit?'* (Interviewer) *'Yeah…because you can tell the dentist how you feel and tell them things that you want to happen in the appointment and the things you don't want'* (Participant group 5, Female 13yrs).

> *'It's more that somebody's actually taking an interest in taking time'* (Participant group 4, mother)

Some children worried about returning to their local dentist with whom they did not have such a positive relationship:

> *'I think it's because the dentist that we've got, they're not like good if I'm honest because they don't tell you stuff'* (Participant group 3, female 12yrs).

'Control and choice'
Agreeing a stop signal, one of the activities suggested in the book, was particularly valued by children and parents/carers. Having a clear understanding of what would happen within the appointment enabled patients to feel more in control. Children also liked the cognitive and behavioural techniques (e.g. distraction, listening to music) and the choices that had been provided to them as result of using the resource:

> *'Normally I'm really scared in the dentist and normally I'll just say I don't need to go. When I read some of this I was like cool and then the dentist kept telling me that you do get to make decisions…then I felt more comfortable*' (Participant group 4, Female, 14 yrs).

> *'They let her have her headphones in, basically, listen to music and she had full control of everything that she was doing and I think that were a big part of her confidence'* (Participant group 2, mother).

Dental professionals' acceptability of the guided CBT self-help approach
In total, 25 dental professionals were interviewed; nineteen dental team members who had been involved in the development of the CBT resource and six additional professionals (three paediatric dentists, one paediatric dental therapist and one dental nurse who had experience of using the CBT resource with patients and a commissioner of dental services). Therefore, the majority (80%) of professionals who provided data on the acceptability of the self-help resource had not used the self-help resource with patients.

Framework analysis revealed four themes and six sub-themes within the data, which are discussed below. The coding templates and analytic framework used to develop the final themes are included in 'Additional file 1'.

Theme 1. 'The value of a CBT self-help resource'
'Anxiety management: an important part of our role'
Dental team members felt that managing anxiety of their patients was important and presented significant challenges.

> *'if we don't help them now they are going to grow up to be adults with a mouth full of rotten teeth who will need very difficult extractions, who are terrified to come in*' (D4, GDP).

> *'it's quite difficult, you know lots of the time the parents/carers are anxious as well so there is no-one really supporting you'* (D7, GDP).

'Benefits of using a CBT self-help resource'
Dental team members were therefore positive about the development of a resource which could aid them in the management of dental anxiety. Perceived benefits of using a CBT self-help approach included: i) reducing children's dental anxiety levels and their reliance on pharmacological approaches to managing their dental care, and ii) helping practitioners understand and manage dental anxiety.

> *'As a clinician this would be a really valuable aid…[…]…from a commissioning point of view, any aid that helps people on the ground to do something has got to be valuable...[…]…the best way to reduce a GA waiting list is not to put more money in. It's to front load with a load of resources to stop it happening in the first place and then load it at the end to stop the recurrence'* (D25, commissioner).

> *'It [anxiety] could be managed with the help of a self-help approach. I think that would be a huge advantage and I think for the patients longer term to be able to have their dental treatment done but without the anxiety and not having that reliance on sedation or general anaesthetic'* (D1, community dentist).

However, practitioners felt that it was important the CBT resource could be used with patients within the time constraints of the NHS dental contract.

> *'I wouldn't want it to be too complicated and I wouldn't want it to be another kind of something that you would have to do long training'* (D11, paediatric dentist).

Theme 2.'Patient suitability and engagement'

It was recognised that there were some individuals for whom the CBT self-help approach may be less suitable. It was suggested that children who had complex needs (e.g. autism) could experience difficulties engaging and this type of approach may not be sufficient to manage patients with high levels of dental anxiety.

> *'[children with] mild autism and Asperger's….perhaps haven't engaged with it quite as well, found it harder…'* (D21, paediatric dentist).

Some professionals also felt that a proportion of patients would not be interested in the resource because of a preference for (or reliance on) pharmacological interventions.

> *'Some patients they just come in and say 'I want sedation''* (D7, GDP).

> *'I think it's to do with targeted stigma associated with psychology being a mental health issue…but if patients and parents/carers are open to it, I think it will be received really well'* (D2, paediatric dentist).

'Parental involvement: beneficial but not essential'

Dental team members who had no experience of using the CBT resource felt that parental engagement would be central to the success of the CBT self-help approach. However, dental team members who had used the resource felt that this was less of an issue and suggested that this was because the CBT resource had incorporated an interactive/guided element, which had enabled children who had not engaged with the resource at home to work through key sections with their dentist.

> *'A lot of these children want to feel better about the dentist…so I think a lot of them like to do the booklet and that's it, it's completely independent from the parents/carers a lot of the time'* (D23, paediatric dentist).

Theme 3. 'Using the resource in the real world'

Some practitioners anticipated difficulties using a CBT self-help resource.

'Confidence'

Dentists interviewed felt that they would have the skills necessary to deliver the intervention. However, those individuals who had experience of using the CBT resource felt it did take some time to adjust to this new way of working with anxious patients. The use of scripts was particular valued by these individuals. Professionals also felt that additional on-line training could be provided to help develop people's confidence in the using of the resource.

'A viable management approach?'

It was suggested that practitioners would value the use of a CBT resource with their patients if they found the resource could be feasibly delivered within their practice.

> *'If it was five minutes at the start of a filling appointment say, yes then I think I could do it'* (D7, GDP).

However, some of those interviewed felt that a proportion of practitioners might doubt the efficacy of CBT or have low levels of motivation to treat dental anxiety and thus be reluctant to use the CBT self-help approach within their practice.

> *'There are certain individuals out there who just don't believe in it'* (D2, Paediatric dentist).

Practitioners recommended the resource be evaluated in different dental settings so that the evidence base could be examined. Most of the practitioners were keen to use and evaluate the use of the CBT self-help resource with their patients on the condition that this could be implemented within the time constraints of their NHS clinics.

Theme 4. 'The whole package'

It was felt that there were various ways in which the CBT self-help resource reduced dental anxiety. Dental team members suggested that one of the key mechanisms to change was the facilitation of positive patient-dentist relationships which led to patients developing their trust in the dentist and subsequently feeling less anxious. Dental team members felt that working through the CBT resource with patients had enabled them to gain a better understanding of the patient's anxiety and thus demonstrate more empathy when interacting with the patient.

> *'it's the whole package that reduces their dental anxiety, but maybe that's what it is….it's been an opportunity to build up a positive relationship with the patient'* (D21, Paediatric dentist).

'Communication and care'

It was suggested that the self-help resource had acted as a communication aid between anxious patients and dentists. The importance of dentists' characteristics and behaviours in reducing patients' anxiety was highlighted within the interviews and many of those interviewed felt the CBT resource would fail if the practitioner delivering it did not interact with children in a positive manner (e.g. wasn't friendly, caring and approachable).

> *'Until that child feels you'll be looking after them as an individual and caring about what they want, then I think they are always going to be a bit resistant'* (D6, GDP).

> *'It's about, I believe, in building up trust and honesty'* (D22, paediatric dental therapist).

Discussion

While there is some evidence that therapist-led CBT is an effective treatment for dental anxiety, there is a lack of research exploring children's, parents/carers and dental team members' needs and preferences in relation to the management of dental anxiety. It is important that users' perspectives are fully considered in the intervention design process to maximise the relevance of the intervention for users and the likelihood that the intervention will be adopted by the target population. Therefore, within phase 1 of the research children, parents/carers and dental team members were involved in developing a CBT resource aimed at reducing children's dental anxiety. One of the specific objectives of the project was to develop a child-centred resource which would be acceptable to key stakeholders and this was achieved through employing a 'Person-based' approach to intervention development (Yardley et al. 2015). In order to ensure the intervention was evidence-based, the Five Areas model of CBT (Williams and Garland 2002) informed the development of the CBT self-help resource. One of the benefits of utilising this specific CBT framework was the model's inclusion of contextual and situational factors. Indeed, the findings from the qualitative interviews highlighted the significance of interpersonal relationships; specifically patient-dentist

communication and trust. Had an 'individualistic' model driven the development of the intervention these interpersonal factors may not have been fully considered.

Phase 2 of the research aimed to investigate the feasibility of evaluating the CBT resource in a randomised control trial (RCT). Therefore data on recruitment and retention/ completion rates associated with patients' use of the CBT resource was collected. Two thirds of children who were invited to participate agreed to take part in the study. Recruitment/response rates are important because they provide an indication of how many patients would need to be approached within a future trial in order to obtain the required sample size. The results from the feasibility study indicate that self-help will not be an appropriate management approach for all children with dental anxiety. Indeed, it is widely recognised that some patients with anxiety-related conditions will not opt for CBT based interventions and that several psychosocial factors (e.g. motivation to change, complexity of life situation, psychological mindedness) may influence a patient's willingness to engage or suitability for CBT (Blenkiron 1999). Within the current research, 86% of the patients who were recruited went on to complete the study which is comparable to completion rates reported in CBT services for adults with dental anxiety (Kani et al. 2015).

The current findings revealed that the use of the CBT self-help resource may be beneficial to reduce children's dental anxiety. This is consistent with a meta-analysis undertaken by Kvale et al. (2004) which revealed behavioural interventions aimed at reducing dental anxiety have a large effect size overall (1.8). However, this meta-analysis focused on interventions for the management of dental anxiety in adults. The findings from the current study suggest that the CBT resource may be an effective intervention for children with dental anxiety. Standard deviation scores and effect sizes in the current study could also be used to inform a sample size calculation for a future trial, however, within a future trial it would be important to establish whether the reduction in dental anxiety associated with the use of the self-help CBT resource is clinically meaningful. The improvement in HRQoL is also interesting and indicates that the CHU-9D measure may be an appropriate instrument to use in a future trial due to it having the required sensitivity to detect changes in HRQoL impacts associated with dental anxiety and oral health. The mean difference of 0.03 which was reported in this study is generally regarded as significant in utility measures (Drummond 2001).

The feasibility study also explored children's, parents/carers' and dental team members' views about the acceptability of the CBT self-help approach. Findings from the stakeholder interviews revealed children, parents/carers and dental professionals viewed the self-help book positively. The qualitative data suggested that the CBT self-help resource may operate on a number of different levels to reduce children's dental anxiety. The provision of preparatory information and use of cognitive and behavioural strategies appeared to increase patients' perceptions of control and reduce dental anxiety. The importance of adequate information provision and cognitive-behavioural strategies in the management of patients with mild to moderate dental anxiety has indeed been highlighted within the literature (Newton et al. 2012). The use of the CBT resource also appeared to facilitate positive patient-dentist relationships and improve communication. Effective patient-dentist communication has been found to play a significant role in reducing dental anxiety (Zhou et al. 2011). It is possible that the efficacy of many self-help interventions could be partly attributable to this type of therapeutic alliance. Indeed there is some evidence that the therapeutic alliance is a key factor in developing feelings of safety and calmness in children with dental anxiety and that this can subsequently lead them to view dental staff in a more positive light (Shahnavaz et al. 2015). The findings from the current study also provided some evidence that parents/carers had learnt effective ways of supporting their children with their anxiety, highlighting the importance of promoting parental involvement in the development and implementation of child-centered interventions.

The final objective of the study was to determine whether preliminary evidence supports continuation to a large scale randomised control trial. The recruitment and retention rates within the current study and the reduction in children's dental anxiety and improvement in HRQoL, following their use of the CBT self-help resource, provide promising results which suggest that this intervention may be a viable approach for the

management of children's dental anxiety. These findings are consistent with previous research which has evidenced the effectiveness of guided self-help CBT in the treatment of child anxiety (Creswell et al. 2014). Therefore, it is proposed that further evaluation of the treatment efficacy and cost effectiveness of the CBT self-help approach is warranted.

While there are challenges with undertaking mixed methods studies (e.g. resources required, integration of data) the mixed methods approach employed within the current study strengthened the quality of this research. Indeed, Medical Research Council guidance for the development and evaluation of complex interventions suggests that feasibility studies benefit from the inclusion of both quantitative and qualitative methods (Craig et al. 2008). In order to maximise the credibility and quality of the research undertaken it is important that individuals are reflexive and consider how their personal experiences, perspectives and roles may influence the research process/findings. Within the current study, three members of the research team had a dual role within the research and were involved in both the design of the research and the delivery of the CBT intervention. It is therefore possible that their in-depth knowledge of the CBT self-help resource could have influenced their confidence in their implementation of the resource. In order to manage this potential issue a communication script was developed to standardise the delivery of the CBT approach. In addition, in order to minimise the likelihood of social desirability bias within the study (e.g. patients feeling the need to provide positive feedback about the CBT self-help resource because they are aware their dentists are part of the research study and they want to please them), all interviews and analysis were undertaken by members of the research team who had no clinical involvement in the child's dental care. Children and parents/carers were also informed that their dental care would not be influenced by their participation in the research and that their responses would be anonymised.

There were a number of limitations to the study. Firstly, it was an uncontrolled treatment development and feasibility study and therefore the design of the study prevents examination of whether the improvements in dental anxiety and HRQoL were due to the intervention itself. It is possible there were treatment effects (e.g. desensitisation) which contributed to the reduction in dental anxiety. Potential confounder variables (e.g. socioeconomic status) could also have influenced the results of the study and these should be fully considered in any future evaluation of the resource. However, the aim of this study was not to evaluate the effectiveness of the CBT self-help resource but to examine whether preliminary results suggest this intervention could and should be tested in a full scale trial. Secondly, within the feasibility study all of the patients with self-reported dental anxiety were invited to trial the resource. At baseline MCDAS scores ranged from 15 to 35 and therefore whilst no threshold scores have been established to identify low/moderate/severe anxiety this range of scores indicates that a proportion of patients had high levels of dental anxiety (maximum score possible was 40). It is recommended that CBT self-help be offered as a low intensity intervention as part of a stepped care approach for the management of mild-moderate anxiety and it is recognised that patients with high levels of dental anxiety are likely to require more complex interventions (Newton et al. 2012). Therefore, the inclusion of this group of patients in this study could have resulted in the underestimation of the treatment effectiveness of the guided CBT self-help resource. Thirdly, it is possible that a sampling bias could have influenced the results of the study. For example, it is plausible that the clinicians who volunteered to take part in the current study had a particular interest in the management of dental anxiety. However, a purposive recruitment strategy was employed to ensure patients and professionals from a diverse range of backgrounds, and with a diverse range of experiences, were represented within the research.

Finally, it should be recognised that the CBT self-help resource was piloted in a community salaried dental service and a hospital paediatric dentistry clinic. Consequently, while general dental practitioner's acceptability of the CBT self-help resource was explored within the current study, the feasibility of implementing the intervention in a primary dental care setting was not evaluated. Therefore, future evaluations would need to evaluate the CBT resources in different dental settings. A large proportion of adults who complete therapist-led CBT for dental anxiety go on to receive dental treatment without the need

for sedation (Kani et al. 2015). However, future research is needed to investigate the possible longstanding benefits of this guided self-help CBT intervention and examine whether the use of this approach can improve children's future engagement with dental services, reduce referrals to specialist services and decrease reliance on pharmacological interventions for the management of dental anxiety.

Conclusion

The CBT self-help resource appears to be a feasible and acceptable intervention for the reduction of dental anxiety in children aged 9-16 years. The promising findings from this study warrant further evaluation of the resource and thus a randomised controlled trial is needed to determine the treatment and cost effectiveness of this self-help CBT intervention compared to usual care. If the results of a further trial confirm the effectiveness of this self-help approach this intervention would provide a viable alternative to the pharmacological management of dental anxiety in children.

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Competing interests

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

Authorship and contributions

The design of the study was conceived primarily by Dr Zoe Marshman, Professor Helen Rodd and Dr Jenny Porritt with Professor Chris Williams, Professor Cathy Creswell, Professor Tim Newton and Professor Sarah Baker. Professor Helen Rodd, Miss Annie Morgan, Mrs Suneeta Prasad and Miss Jennifer Kirby developed the clinical aspects of the protocol and were responsible for clinical data collection. The health economic aspects of the design of the study were conceived by Dr Katherine Stevens. Dr Ekta Gupta worked as the Research Assistant on the study and contributed to data analysis and interpretation. All authors contributed to project team meetings and study development. Dr Jenny Porritt and Dr Zoe Marshman wrote the draft and subsequent revisions of the manuscript. All authors contributed to critical revision of the manuscript for important intellectual content and approved the final manuscript for submission.

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Table 1. Summary of themes which informed the development of the CBT self-help resource

Themes/sub-themes which emerged from stakeholder interviews	How this informed the content/format/delivery of the CBT resource
Theme 1: 'pure versus guided self-help' • 'Advantages and disadvantages of a pure self-help approach' (e.g. less practitioner time required however reliance on high levels of motivation, low levels of perceived value/ efficacy). • 'Advantages and disadvantages of a guided approach' (e.g. would require more time but higher levels of perceived value/efficacy, time required needs to be feasible). • 'Relationship building' (e.g. the resource should help build positive and trusting patient-dentist relationships so the dentist should have some involvement in the delivery of the resources).	• The analysis of this data revealed stakeholders had a preference for the guided self-help approach delivered by the patient's dentist so a guided CBT resource was developed. • The CBT self-help resource includes a variety of tools that facilitate effective communication and positive relationships between the patient and dentist (e.g. dentist message). • The CBT self-help resource is designed in such a way that it could be used flexibly by practitioners. Practitioners can focus on reading/working through specific 'self-contained' and 'brief' sections of the resource that are most helpful for their patient and are most feasible for them to work through in their dental setting.
Theme 2: 'Supporting everyone involved' • 'Parents/carers' difficulties and challenges' (e.g. helplessness, responsibility/pressure, negative emotions). • 'Ways in which parents/carers have tried to manage their child's anxiety' (e.g. withholding information, persuasion/pressure, reassurance, distraction, positive reinforcement). • 'Parent's need for support' (e.g. better understanding of child's anxiety, know what they can do to help their child). • 'Needs of dental team' (e.g. Help with understanding patients' anxiety and what can be done in practice to help manage anxiety, specific information about how to introduce the CBT book (e.g. script)).	A supporting parent resource was developed which aimed to help parents/carers: • Understand their child's dental anxiety and reflect on how helpful/unhelpful their own thoughts and behaviours might be. • Develop ways of supporting their children with their anxiety. A supporting resource for the dental team was developed which included the following: • Information about to use the guided CBT resource with patients (e.g. scripts for introducing the CBT self-help resource etc.). • General tips and techniques for the management of dental anxiety. An assessment tool was also included within the 'dentist message' section of the children's CBT resource to help dental practitioners better understand their patients' anxiety/needs.
Theme 3: 'Facilitators: engaging, informative and accessible' • 'Informative' (e.g. information on treatments, equipment, procedures) • 'Simple and age-appropriate' • 'Interactive' (e.g. activities to complete) • 'Mixed formats' (e.g. online and paper based)	A paper-based CBT self-help resource was produced so that the resource could be used easily by patients and dentists within dental clinics. However, as a result of this feedback we have also developed an online portal where the CBT resource and supporting resources can be accessed for free (www.llttf.com). A number of activities and illustrations are included within the resource to optimise engagement and children, parents/carers and dental team members were fully involved in the development and revision of the content/presentation of material included to ensure the CBT resource was age appropriate and accessible.
Theme 4: 'Potential barriers' • 'Too much information' • 'Not enough time'	The CBT self-help resource is designed in such a way that it could be used flexibly with patients and dentist to overcome this possible barrier. Therefore, it is not necessary for patients or dentists to require large amounts of time to read/work through the whole CBT resource in one sitting.

Table 2. CBT framework and techniques used in the 'Your teeth. You are in control' the self-help CBT resource

Five Areas Model of CBT - main areas targeted	**Information/activities included in the CBT resource 'Your teeth you are in control' and supporting resources**
i) Altered thoughts and ii) altered feelings	The CBT self-help resource: • Provides information on how common dental anxiety is to normalise the children's feelings (e.g. 'Not everyone loves their dentist' section). • Contains information about the common unhelpful thoughts that children with dental anxiety experience (using data provided by children in qualitative interviews) and how they can challenge these helpful thoughts. • Provides information on cognitive techniques/tools children can use when at the dental clinic (e.g. 'Here's how to take control' section). • Contains procedural and treatment information (e.g. 'The facts' section). • Encourages children to reflect on their experiences and reappraise their anxiety (e.g. 'Now you've finished' section).
iii) Altered behaviours and iv) physical symptoms	The CBT self-help resource: • Provides information on specific behavioural techniques/tools children can use (e.g. 'Here's how to take control' section). • Encourages patients and dentists to develop a shared treatment plan (e.g. 'Now make a plan' section). • Includes a communication tool which can be used by patients to communicate information about their anxiety to the dentist ('Dentist message' section). • Encourages children to write down the specific cognitive and behavioural techniques they are going to use when they next visit the dentist (e.g. 'Preparing for next time' section). • Encourages the use of positive reinforcement to increase probability that helpful behaviours, such as attending the dentist and/or receiving treatment, will be repeated (e.g. 'Time for a reward' section).
v) Situational influences of dental anxiety (e.g. improving patient-dentist relationship, dealing with parental anxiety)	The CBT self-help resource: • Requires patients and dentists to work through parts of the resource together building up trust and a therapeutic patient-dentist relationship. • Contains supporting resources for dental team members and parents/carers to facilitate a 'team approach' to the management of children's dental anxiety.

Table 3. Characteristics of young people purposively sampled for interviews in the feasibility study (phase 2)

Participant group number	Participant's details	Deprivation quintile (1= least deprived, 5=most deprived)	Dental treatment	Engagement with resource at first visit (written in guide)
Participant group 1	Male (15yrs) and mother	5	Dental restorations and extractions	Yes, partly (able to discuss)
Participant group 2	Female (12yrs) and mother	2	Dental restorations and extractions	Not at all (no idea)
Participant group 3	Female (13yrs) and mother	3	Fissures sealants, extractions and restorations	Yes, partly (able to discuss)
Participant group 4	Male (14yrs) and mother	2	Dental restorations	Yes, partly (able to discuss)
Participant group 5	Female (12yrs and mother	1	Fissure sealants, restorations and extractions	Yes, fully (written in guide)
Participant group 6	Female (14yrs), mother and father	5	Fissure sealants, restorations and extractions	Yes, fully (written in guide)
Participant group 7	Female (10yrs) and father	4	Fissure sealants and extractions	Yes, fully (written in guide)
Participant group 8	Male (13yrs) and mother	3	Dental restorations and extractions	Not at all (no idea)
Participant group 9	Female (14yrs) and mother	1	Fissures sealants and extractions	Yes, fully (written in guide)
Participant group 10	Female (11yrs) and mother	4	Fissures sealants and extractions	Yes, fully (written in guide)
Participant group 11	Male (13yrs) and mother	3	Fissure sealants and restorations	Yes, partly (able to discuss)

Table 4. Data for participants who completed the feasibility study (phase 2)

Variables	N / mean
Participants completed CBT self-help resource	N=48
Mean age	Mean =12.3 years (SD=1.9)
Gender	
Male	N=15
Female	N=33
Ethnic Background	
White British	N=45
Any other group (English Caribbean & Asian Pakistani)	N=3
Deprivation score	
1st Quintile (least deprived)	N=9
2nd Quintile	N=5
3rd Quintile	N=9
4th Quintile	N=10
5th Quintile (most deprived)	N=15
PAST DENTAL HISTORY	
Past dental general anaesthetic	
Yes	N=16
No	N=30
Not known	N=2
Previous inhalation sedation	
Yes	N=4
No	N=44
Reason for referral	
Caries	N=36
Orthodontic extractions	N=10
Trauma	N=1
Other	N=1
Engagement with CBT resource at 'intervention appointment 1' visit	
Yes, fully (written in guide)	N=26
Yes, partly (able to discuss)	N=15
Not at all (no idea)	N=6
Data missing	N=1
Completed treatment following use of CBT self-help resource	
Yes	N=43
Treatment ongoing	N=5
Pharmacological intervention(s)	
Referral letter stated need for GA	N=10
Child received GA only	N=3
Referral letter stated need for sedation	N=19
Child received inhalation sedation only	N=38
Child received GA and inhalation sedation	N=3

Appendix 1

i) Interviews with children and parents/carers (acceptability study): coding template and analytic framework

Coding method	Initial category	Codes	Final themes and sub-themes
Developed a priori	Changes in anxiety	• Thoughts, feelings, behaviour, physical symptoms (past, current)	**Theme 1: 'A positive experience'** 'Increased understanding' ' Less anxiety, more confidence' 'Additional benefits'
	Acceptability	• Attitudes towards resource (likes/dislikes) • Past/present/future use	
	Usability	• Barriers (e.g. memory) • Facilitators (e.g. support)	**Theme 2: 'Barriers to engagement'** 'Overcoming barriers'
Data-driven	Relationships	• Information and communication (parent and dentist) • Control • Trust	**Theme 3:'Importance of communication and positive relationships'** 'Communication and care' 'Control and choice'

ii) Interviews with dental team members: coding template and analytic framework

<table>
<tr><th>Coding method</th><th>Initial category</th><th>Codes</th><th>Final themes and sub-themes</th></tr>
<tr><td rowspan="4">Developed a priori</td><td>Attitudes</td><td>• Attitudes towards anxiety management (importance of role)
• Attitudes towards CBT self-help approach (advantages/disadvantages)
• Acceptability (intention to use)</td><td rowspan="3">Theme 1:'The value of a CBT self-help resource'

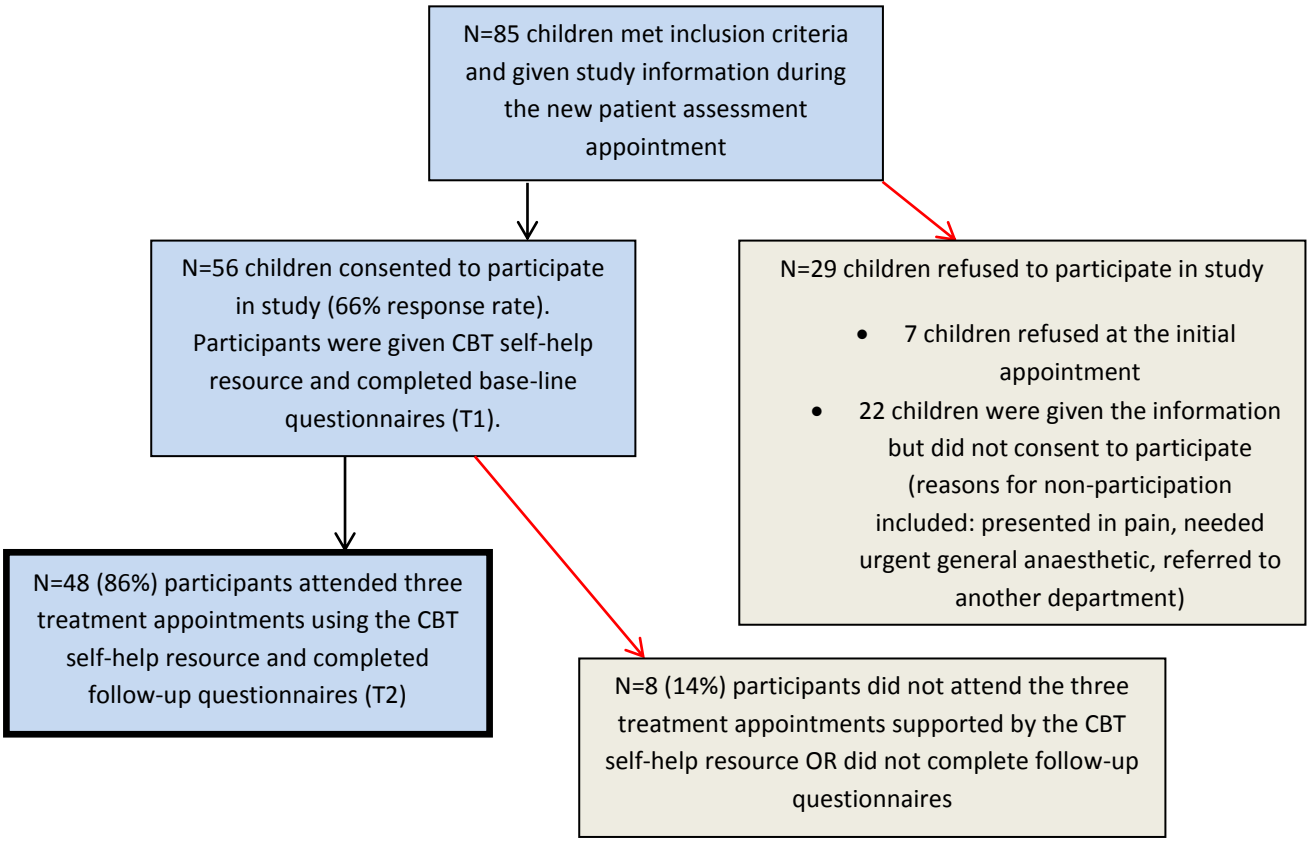
'Anxiety management: an important part of our role'
'Benefits of using a self-help resource'

Theme 2:'Patient suitability and engagement'

'Parental involvement: beneficial but not essential'</td></tr>
<tr><td>Past behaviour / experience</td><td>• Past experience (using self-help tools, managing dental anxiety)</td></tr>
<tr><td>Subjective norms</td><td>• Expectations of others (e.g. parents/carers, children, peers) and importance of these expectations</td></tr>
<tr><td>Perceived behavioural control related to use of resource</td><td>• Confidence to use self-help resource
• Barriers/difficulties
• Facilitators</td><td>Theme 3: 'Using the resource in the real world'

'Confidence'
'A viable management approach?'</td></tr>
<tr><td>Data-driven</td><td>Understanding change</td><td>• Care/personalities
• Communication</td><td>Theme 4: 'The whole package'

'Communication and care'</td></tr>
</table>


N=85 children met inclusion criteria and given study information during the new patient assessment appointment
N=56 children consented to participate in study (66% response rate). Participants were given CBT self-help resource and completed base-line questionnaires (T1).
N=29 children refused to participate in study
7 children refused at the initial appointment
22 children were given the information but did not consent to participate (reasons for non-participation included: presented in pain, needed urgent general anaesthetic, referred to another department)
N=48 (86%) participants attended three treatment appointments using the CBT self-help resource and completed follow-up questionnaires (T2)
N=8 (14%) participants did not attend the three treatment appointments supported by the CBT self-help resource OR did not complete follow-up questionnaires