NETSCC, HTA

9th May 2011

FiCTION Feasibility Study

FiCTION Feasibility Study

Filling Children's Teeth: Indicated or Not? Feasibility Study

Protocol ID: NCTU:FS77044005

Protocol Version 1.1

Date: 14/02/2011

Funded by the NIHR HTA

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2. PROTOCOL SIGNATURE PAGE

2.1. PROTOCOL AUTHORISATION SIGNATORIES

Signature ……. Date……..
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Signature ……. Date……..
Dr Nick Steen Statistician

Signature ……. Date……..
Mr Chris Speed, Trial Manager

3. CONTENTS

4. GLOSSARY OF ABBREVIATIONS

CI	Chief Investigator
GCP	Good Clinical Practice
NCTU	Newcastle Clinical Trials Unit
NIHR	National Institute for Health Research
NIHR HTA	NIHR Health Technology Assessment programme
PI	Principal Investigator
R&D	Research and Development

5. KEYWORDS

Caries prevention, primary teeth, prevention, paediatric dentistry, restoration, fillings, qualitative, primary care, focus group.

6. RESPONSIBILITIES

Sponsor: University of Dundee

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
1. Study preparation	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor	
	b) Secure and administer funding for the Study.	Sponsor	Chief Investigator
	c) Secure and contract for the supply of resources including medicinal products/devices/CRO services.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor	
2. Applications and Registration	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor	
	b) Prepare Participant information sheet and consent form, including where appropriate consent to providing Participant tissue, sample, medical data or other material to the Sponsor and other relevant documents prior to ethics submission.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Prepare and submit ethics application.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Register the Study with an appropriate protocol registration scheme.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Obtain NHS permission.	Sponsor	
3. Protocol Amendments	a) Prepare and submit proposed substantial amendments of the Protocol to the regulatory authority(ies), relevant ethics committee and NHS Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
4. Study Conduct	a) Ensure that legislation in relation to research is followed	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	b) Ensure that the study team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	c) Ensure that no Participant is recruited until a favourable ethical opinion has been provided	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and Clause 2 of this Agreement	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol.	Sponsor	Chief Investigator / Newcastle Clinical Trials
	g) Ensure that the rights of individual Participants are protected whilst participating in the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	h) Maintain and archive Study documentation.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	i) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
	j) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	k) Report suspected research misconduct.	Sponsor	Chief Investigator
	l) Notify the regulatory authority(ies) of the end of the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	m) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
5. Data Management	a) Design of questionnaires and database.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure appropriate analysis of data.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
6. Publication	a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
7. Archiving	a) Ensure that all Study records are archived appropriately on conclusion of the Study and retained for seven (7) years	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

7. PROTOCOL SUMMARY

Full Title:	Filling Children's Teeth: Indicated or Not? Feasibility Study
Short title:	Short Title: FiCTION Feasibility Study
Protocol version:	0.1
Protocol date:	24/03/09
Chief Investigator:	Dr. Nicola P Innes
Sponsor:	University of Dundee
Funder:	NIHR HTA
Study design:	Mixed qualitative & quantitative methods feasibility study for the FiCTION trial including focus groups and/or face to face interviews with children, parents and dentists and postal questionnaire survey with dentists.
Feasibility Study objectives:	1. To assess dentists' preparedness to enrol in the FiCTION Trial. 2. To explore the issues of running the FiCTION pilot rehearsal trial with service user & service provider involvement panels. 3. To inform the decision of whether to proceed to the full FiCTION trial and whether any refinements to the design or conduct of that trial are warranted
Study sites:	Dental practices in Cardiff; Dundee/Glasgow; London; Newcastle; Leeds/Sheffield.
Study population feasibility study	Dental practices eligible to participate in the main FiCTION trial. Dentists who have participated in the FiCTION Pilot Rehearsal Trial. Children and adults who have been approached to take part in the Pilot Rehearsal Trial in the participating practices.
Study duration:	15 months

8. INTRODUCTION

8.1. BACKGROUND

The lack of evidence for the effective management of dental decay in children's primary teeth is causing considerable uncertainty for the dental profession and patients. In particular, the apparent failure of conventional dental fillings to prevent pain and sepsis for UK children in primary care [1] has prompted much debate. At the present time, teaching in UK dental schools is based on guidance from the British Society of Paediatric Dentistry (BSPD) which includes the recommendation that the optimum treatment of decay in primary teeth should be its removal, followed by the placement of a conventional filling to replace lost tooth tissue [2, 3]. However, these recommendations are largely based on evidence for the effectiveness of fillings obtained from studies conducted in either a secondary care or specialist paediatric practice setting. While both the volume and quality of the research on which the guidance is based is limited, it is acknowledged that fillings provided in specialist clinical environments can be effective [4]. It is the generalisability of this evidence to a primary care setting which is in question, and in particular the barriers, e.g. time, to providing fillings of sufficient quality to prevent pain and sepsis.

In the UK, the majority of dental care for children is provided in primary care by general dental practitioners (GDPs). Three recent studies, conducted in general dental practice in the UK, have provoked the current debate of what is appropriate and effective care for children with decay in primary teeth. The first of these was a retrospective case note study, based on a group of 50 GDPs' patient records, which suggested that placing a filling compared with leaving the tooth unfilled did not improve the clinical outcome in terms of dental pain and sepsis [1]. In fact, the likelihood of children with filled teeth experiencing dental pain or sepsis was similar to that reported for the second study of 481 children who attended two general dental practices with a practice policy of leaving asymptomatic carious primary teeth unrestored, focussing on a preventive strategy alone to manage them [5]. The third, and most recent, was a randomised controlled trial involving 18 GDPs and, arguably, provides the most robust evidence. The results demonstrate the ineffectiveness of the conventional, surgical approach (that is drilling out decay and placing a filling) to treating decay in general dental practice. This trial showed a failure rate in terms of pain and sepsis, after two years, approaching that reported by the previous two studies for unrestored teeth [6].

Perhaps because of perceived ineffectiveness, the traditional "drill and fill" methods of managing decayed primary teeth are not popular with GDPs [7]. Less than 10% of decayed teeth in 5 year-old children are currently filled [8]. However, a recent Cochrane review [9] found that emerging biologically-orientated strategies for managing decay (sealing some of the decay within the tooth rather than drilling it all out) are effective. In addition, a "biological" method of managing primary teeth by sealing in the decay with preformed metal crowns (PMCs) has been found to be both effective at preventing pain and sepsis, and acceptable to children, parents and GDPs [6].

Currently GDPs in the UK are providing care for children under different funding systems. Whilst the implication of the funding systems on the type and quality of care is unknown, there is universal agreement that guidance for the effective management of decay is needed. In Scotland, the capitation and fee per item of service system is in operation, and to assist healthcare workers and patients the Scottish Dental Clinical Effectiveness Programme is currently in the process of developing national guidance for the management of decay in children. In England and Wales many Primary Care Trusts (PCTs) are now seeking to secure adherence to best practice guidance as part of their clinical governance responsibilities when commissioning dental primary care services. However, the lack of direct evidence relevant to the setting where the vast majority of child dental care is carried out, general dental practice, and the discrepancy between the evidence for restorative management of decay in the primary and secondary care settings, complicate the development of the process of care for what is the most common disease of young children. There is a gulf between the management strategies for decayed primary teeth recommended by the BSPD (and taught in UK dental schools), and the treatment currently being provided by GDPs. As yet, there is insufficient evidence on which to

base a recommendation as to which of three possible management strategies: the surgical approach (tradition fillings); the biological approach (including sealing caries to stop its progress); or prevention alone where no fillings are placed, is the most effective at managing dental decay in children in primary care. The implication of this research is likely to be a change in policy for service and education in the NHS and beyond.

8.2. RATIONALE FOR CURRENT STUDY

The definitive, multi-centre FiCTION trial will address the research question "What is the clinical and cost effectiveness of filling caries in primary teeth, compared to no treatment?" The main FiCTION trial will also compare the relative clinical and cost effectiveness of the following three treatment strategies:

Surgical management of decay, with best practice prevention
Surgical management is commonly known as the 'drill and fill' method. In this treatment the tooth is numbed with a dental injection, then mechanical removal of the decay is carried out using a rotary instrument (drill) and a filling is placed in the tooth.

Biological management of decay, with best practice prevention
In this treatment arm, cavities are assessed clinically for whether the decay is active and if so, it is sealed from the oral cavity by application of an adhesive filling material, or by covering with a metal crown. Decay may, on occasion, be partially removed prior to the tooth being sealed. Injections are rarely needed.

No Fillings, best practice prevention alone
With good oral hygiene it is possible to slow down the rate of tooth decay and prevent toothache and infection of the gums with sepsis. For the best practice prevention alone arm, no drilling, filling or sealing of primary teeth will occur. Dentists and other members of the dental team will base treatment plans for patients on best practice preventive care for teeth and oral health. Fluoride varnish and fissure sealant may be applied.

The concurrent rehearsal pilot study (ISRCTN77044005) will assess whether the proposed design for the main FiCTION trial is practicable.

The rationale for this feasibility study is to allow researchers to fully explore a range of factors that might impact upon the successful implementation of the main FiCTION trial from the perspective of service providers and service users.

9. STUDY OBJECTIVES

1. The FiCTION feasibility study will investigate practices' and dentists' preparedness and willingness to participate in the main FiCTION Trial.

2. The FiCTION feasibility study will also explore the issues of running the proposed FiCTION Trial from the service providers' and service users' perspective by using provider and consumer involvement panels drawn from those providers and users participating in the FiCTION Pilot Rehearsal Trial.

Ultimately, the results of the FiCTION feasibility study (including the Pilot Rehearsal Trial - ISRCTN77044005 - REC Ref 10/S1402/8) will inform the decision of whether to proceed to the full trial and whether any refinements to the design or conduct of that trial are warranted.

10. STUDY DESIGN

The feasibility study will make use of a range of investigative techniques including:-

i) a survey of dental practices to assess dentists' preparedness to enrol in such a trial and to assess likely practice recruitment
ii) a service user involvement panel (focus group and/or face to face interview);
iii) a service provider involvement panel (focus group) comprising dentists and dental practice staff who have participated in the FiCTION Pilot Rehearsal Trial.

10.1. SURVEY OF GENERAL DENTAL PRACTICES TO ASSESS RECRUITMENT OF REPRESENTATIVE PRACTICES

To assess the feasibility of recruiting a representative group of 50 practices to the main FiCTION trial we will utilise existing collaborative links with Practitioner Services Division Scotland (PDS) and NHS Business Services Authority England/Wales (BSA)/Primary Care Trusts to identify all practices in the catchment areas of the five proposed centres providing non-specialist NHS care to children. The PDS will provide a randomised list of these practices for the Scottish-based centre (Dundee/Glasgow), and the Newcastle Clinical Trials Unit will randomise the list provided by PCTs for the remainder of the UK centres (Cardiff; London; Newcastle; Leeds/Sheffield). We will produce a list of 40 practices in each centre (200 in total). We will send a capacity and infrastructure questionnaire to the Practice Principal in each of the 200 practices. This will allow us to identify which practices could potentially host FiCTION. For those practices where the infrastructure is in place to 'host' the FiCTION trial, we will send each GDP listed at the practice a questionnaire to assess interest in taking part in FiCTION, willingness and preparedness to deliver a randomly selected intervention arm

Practices that demonstrate that they can host and have at least one GDP interested will be 'banked' and approached to take part in the main trial.

Based on recruitment to other trials within dental primary care [10] we currently estimate that 50% of practices approached would be willing to participate in this trial and eligible, therefore of the 200 practices approached we would expect around 100 to be willing and eligible, making our target total of 50 practices readily achievable. An invitation to participate in the main FiCTION trial will then be sent to these 100 practices. The deadline for responding to this will be 2 weeks after the second reminder letter of invitation. Should the main FiCTION trial proceed, any changes resulting from the FiCTION pilot rehearsal trial and feasibility study will be incorporated into it and 10 practices from each area who have agreed to participate will then be randomly selected for inclusion in it with the remaining practices being placed on a waiting list.

10.2. SERVICE USER & PROVIDER INVOLVEMENT

Embracing contemporary approaches to patient involvement in research, children and their parents will be involved throughout the feasibility study and subsequent trial to investigate their perspectives on possible ethical issues and a number of other important aspects of the trial. A panel of children and their parents and another of dental practice staff will be utilised and all interviews and focus panel interactions will be recorded and analysed independently by two investigators. Focus group and/or face to face interview sessions will last a total of 90 minutes and each focus group and/or interview will convene once during the study.

10.3. PANEL OF SERVICE USERS:

During the pilot trial: a panel of service users (5 children and their parents) and/or one face to face interviews will be drawn from children and their parents who have been approached to take part in the pilot rehearsal trial in the Sheffield area. This will be used to inform on how to help minimise attrition

among participants by exploring their experiences of the pilot trial and assessing the value of strategies to retain participants e.g. the use of marketing materials [e.g. calendars, key rings, greeting cards, pens, mouse mats etc.]. This focus group and/or face to face interview will also explore participants' experiences and preferences for the treatment strategies in more depth. In addition, the group will inform development of trial materials, and discuss methods to promote the study, contribute to developing the information sheets and consent forms for participants in the main FiCTION trial and assess the acceptability of the proposed questionnaires for collecting outcome data. All three treatment arms will be represented in the group.

10.4. PANEL OF DENTISTS WHO HAVE PARTICIPATED IN THE PILOT TRIAL:

A panel of Pilot Rehearsal Trial dentists and other members of the practice team will be brought together at the end of the Pilot Rehearsal Trial to investigate their experiences, to inform on any improvements which could be made to the design and conduct of the study for the main trial and also to explore strategies to promote retention of practices within the study. There will be a total of 5 people on this panel.

11. STUDY OUTCOME MEASURES

Quantitative:
The survey of general dental practices to assess average numbers of eligible children, clinical equipoise, ability to 'host' and willingness to join the main FiCTION Trial will provide us with data on the likely participation rates for the main FiCTION trial.

Qualitative:
The service user focus group and/or face to face interview will provide information about refinements to the trial materials (PIS, questionnaires etc), the treatment strategies proposed for the main FiCTION trial, and ways of promoting the trial to participants.

The service provider focus group will provide information and insight into participation in the proposed FiCTION trial.

12. PARTICIPANT ENTRY

12.1. INCLUSION CRITERIA

12.1.1. Survey of general dental practices to assess recruitment of representative practices:

Practices must be in the catchment areas of the proposed centres (Cardiff; Dundee/Glasgow; London; Newcastle; Leeds/Sheffield) for the FiCTION trial, providing non-specialist NHS care to children.

12.1.2. Service users:

Children with experience of dental caries and their parents / caregivers who have been approached to take part in the FiCTION Pilot Rehearsal Trial in the Sheffield area will be eligible to be invited to participate.

12.1.3. Service providers study:

Participants must be staff from dental practices taking part in the FiCTION Pilot Rehearsal Trial.

12.2. EXCLUSION CRITERIA

- Children who are accompanied by an adult who lacks the legal or mental capacity to give informed consent.
- Patients with a medical condition requiring special considerations with their dental management, e.g. cardiac defects, blood dyscrasias.
- Patients currently involved in any other research which may impact upon this study.

12.3. WITHDRAWAL CRITERIA

If at any point during the focus groups a participant wishes to withdraw from the panel of users or providers that wish will be respected. Permission to use the anonymised data collected up to the point of withdrawal will be sought.

13. STATISTICS AND DATA ANALYSIS

13.1. QUESTIONNAIRE

Analyses on the postal questionnaire survey to dentists will be descriptive looking at numbers of child patients (to ascertain whether they see sufficient patients), % of dentists in equipoise, % of practices with web access, electronic databases and X-ray technology.

13.2. FOCUS GROUPS

All focus groups and interviews will be recorded and transcripts analysed using content analysis as described by Huberman and Miles [11]. Content analysis is used as a means of analysing the content of people's communication and varies in its degree of abstraction and conceptualisation ranging from a simple word count and examining the manifest content of the words spoken to higher levels of conceptualisation (latent content).

13.3. DATA COLLECTION AND RETENTION

To preserve confidentiality, all participants will be allocated a unique study identifier, which will be used on all data collection forms and questionnaires; names or addresses will not appear on completed questionnaires, focus group and/or face to face interview transcripts. In the transcriptions from the focus groups and/or face to face interviews pseudonyms will be used to preserve anonymity. Only a limited number of members of the research team will be able to link this identifier to patient-identifiable details (name & address) which will be held on a password protected database. All study documentation will be held in secure offices, and the research team will operate to a signed code of confidentiality. Transmission of identifiable data between practices, coordinating centres, the NCTU and the University of Dundee (the study sponsor) will be by secure fax, registered post or carried by a study team member. A clinical data management software package (Symphony) will be used for data entry and processing, allowing a full audit trail of any alterations made to the data post entry. Original questionnaires, audio files, transcripts and consent forms will be securely archived at the University of Dundee for 7 years following publication of the last paper or report from the study.

14. REGULATORY ISSUES

14.1. ETHICS APPROVAL

The conduct of this study will be in accordance with the ethical principles set out in the Declaration of Helsinki (2008).

Ethical and R&D approval of the protocol will be sought prior to commencement of the study. Local approvals (site specific assessments) will be sought before recruitment commences at each site (general dental practice).

14.2. CONSENT

14.2.1. Focus Groups

The parent(s)/legal guardian(s) of all children in the study will provide written informed consent before any focus groups or interviews are undertaken and a participant information sheet will be provided to facilitate this process. In so far as possible, and with the agreement of the parent(s)/legal guardian(s), participating children will also be asked to provide written or oral assent.

As part of the consent process parent(s)/legal guardian(s) must agree to researchers & regulatory representatives having access to their medical records for monitoring and audit purposes.

Parent(s)/legal guardian(s) will also be informed that they have the right to withdraw from the study at any time. The right to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time from the focus groups without giving reasons and without prejudicing further dental treatment they may receive.

The service providers that have taken part in the FiCTION Pilot Rehearsal Trial (ISRCTN77044005) will be asked to give informed consent prior to participation in the focus groups.

14.2.2. Postal questionnaire survey of general dental practices to assess recruitment of representative practices

The return of a completed questionnaire will be taken as implied consent to participate. The return of an uncompleted questionnaire will be assumed to mean consent to participate has not been given and no further contact with the practice will be made with reference to the feasibility study.

14.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and the Sponsor organisation will ensure that the study is registered under the Data Protection Act.

14.4. INDEMNITY

Indemnity in respect of protocol authorship will be provided through a Dundee, Leeds, Sheffield and Newcastle Universities' public liability insurance. Indemnity in respect of study management will be provided by the University of Dundee, in its role as sponsor. There is no provision for indemnity in respect of non-negligent harm.

14.5. SPONSOR

University of Dundee will act as the main sponsor for this study. Delegated responsibilities will be assigned to the Newcastle Clinical Trials Unit.

14.6. FUNDING

The NIHR HTA is funding this study. There is provision to reimburse participants for taking part in the focus groups.

14.7. AUDITS

The study may be subject to inspection and audit, as part of their routine 10% or 'for cause' by the University of Dundee under their remit as sponsor and by other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

15. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through the Newcastle Clinical Trials Unit.

16. PUBLICATION POLICY

The results of the study will be published as a report for the NIHR HTA, and may be published as research papers in academic journals. Each of the participating PIs will be eligible for authorship on the NIHR HTA report. The CI (Nicola Innes) will be first author on the NIHR HTA report. The study may be presented at scientific conferences and other similar events. No individual patient participating in the trial will be identified from any study report. Authorship on peer-reviewed publications arising from this pilot rehearsal trial will include the chief investigator, grant co-applicants and members of the clinical trials coordinating team (statistician & Trial Manager). The NIHR HTA will be acknowledged on each publication.

17. REFERENCES

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18. APPENDICES

18.1. COVERING LETTERS, PIS'S, CONSENT FORMS, ASSENT FORM

Newcastle Clinical Trials Unit
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4th Floor, William Leech Building
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

Dear (name GDP)

Re: FiCTION: Filling Children's Teeth: Indicated or Not? : Feasibility Study.

We are writing to you on behalf of the FiCTION team to ask if you would be able to complete and return the enclosed questionnaire.

The main FiCTION trial will start in 2012 and is funded by the National Institute for Health Research Health Technology Assessment programme. The trail will be comparing three different methods of treating caries in the primary dentition (See http://www.hta.ac.uk/project/1783.asp). However, before commencing the full trial, we are running a Feasibility Study. An information sheet is included with this letter.

Part of this feasibility study requires us to conduct a postal questionnaire survey with a number of randomly selected dental practitioners to assess clinical equipoise and willingness to take part in the main FiCTION trial.

We would greatly appreciate it if you could return the completed questionnaire to us in the pre-paid envelope within the next two weeks.

By returning the completed questionnaires to us you are not signing up the practice to take part in the main FiCTION trial. Formal approaches to take part will be made at a later date.

If you do **not** wish to be contacted about FiCTION again then please return your blank questionnaire to us. That will stop us bothering you any further.

If you have any other questions you can call up the study team in Dundee on 01382 425 760 (Dr Nicola Innes).

Many thanks in advance for your assistance.

Yours sincerely

Covering letter equipoise V1.0 25/10/10

Newcastle Clinical Trials Unit
Institute of Health and Society
4th Floor, William Leech Building
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

Dear (name of GDP)

Re: FiCTION: Filling Children's Teeth: Indicated or Not? : Feasibility Study.

We are preparing to conduct a clinical trial (FiCTION) which investigates the best way to manage caries in young children: we are writing to you on behalf of the FiCTION team to ask if you would be kind enough to complete and return the enclosed questionnaire please.

The main FiCTION trial is a trial comparing three different methods of treating caries in the primary dentition (See http://www.hta.ac.uk/project/1783.asp).

1. Surgical management of decay, with best practice prevention
2. Biological management of decay, with best practice prevention
3. No fillings, best practice prevention alone

The main FiCTION trial will start in 2012 and is funded by the National Institute for Health Research Health Technology Assessment programme. However, before commencing the main trial, we are running a Feasibility Study. An information sheet about this has been included with this letter.

Part of this Feasibility Study requires us to conduct a postal questionnaire survey with a number of randomly selected dental practices to assess ability be a research site for the main FiCTION trial.

We have addressed this questionnaire to you as the Practice Principal; however you may wish to pass it to a colleague to complete and return if you feel this would be more appropriate.

We would greatly appreciate it if you could return the completed questionnaire to us in the pre-paid envelope within the next two weeks.

One further aspect of the Feasibility Study we need to undertake is a postal questionnaire survey of a selection of dentists to assess how willing dentists would be to deliver one of the three approaches to managing the carious primary dentition selected at random as part of the clinical trial. It may be that in the coming weeks you and your colleagues at the practice receive the questionnaire too.

By returning the completed questionnaires to us you are not signing up the practice to take part in the main FiCTION trial. Formal approaches to take part will be made at a later date.

If you do **not** wish to be contacted about FiCTION again then please return your blank questionnaire to us. That will stop us bothering you any further.

If you have any other questions you can call up the study team in Dundee on 01382 420 050 (Dr Nicola Innes).

Many thanks in advance for your assistance.

Yours sincerely

Covering letter to Principal V1.0 25/10/10

FiCTION TRIAL

Managing Decay for Children

Filling Children's Teeth: Indicated or Not? (FiCTION)

FiCTION Feasibility Study

Dentists' Postal Questionnaire Information Sheet

What is the FiCTION study?

FiCTION is a multicentre trial funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA), comparing 3 different methods of treating caries in the primary dentition (See http://www.ncchta.org/project/1783.asp). However, before commencing the full trial, we are running a feasibility study to assess dentists' willingness and capacity to take part in the main FiCTION trial. Part of this feasibility study includes a postal questionnaire survey.

Before you decide about taking part it is important for you to understand why the research is being done and what it would involve for you. We would be grateful if you would take some time to read the following information carefully.

What is the FiCTION Feasibility Study?

As you will be aware, traditional methods for restoring carious primary teeth (local analgesia, complete removal of caries and restoration) have recently been challenged and there is uncertainty as to the relative effectiveness of different approaches. The FiCTION Trial will compare three different treatment approaches for managing decayed teeth in children aged 3 to 11 to find out which is the most effective in general dental practice. This question of effective treatment for the primary dentition is fundamental to delivering effective dentistry for children in the primary care setting, and the FiCTION Trial will provide some definitive answers including which approach will reduce pain and sepsis and which is preferred by children. More details on the three treatments being compared can be found in the accompanying flyer.

Before we run the FiCTION Trial we are carrying out a Feasibility Study to assess general dental practices' and dentists' ability and willingness to participate in the trial. This will give us information on a range of topics including the number of practices who provide care for children with dentinal caries, the level of interest in the topic area amongst practitioners, clinical equipoise regarding the management of dental caries in children, and access within the practice to the internet.

To find this information out, we would like a representative sample of practices to take part in a postal questionnaire survey. The questionnaire is included with this information sheet.

Why have you asked me to take part?

Your practice has been selected random as being potentially eligible to take part in the FiCTION Trial, and for this reason you are being offered the opportunity to take part in the postal questionnaire survey.

What do I need to do to participate in the FiCTION Feasibility Study?

We would like to you complete the enclosed questionnaire and return it to us in the prepaid envelope preferably within the next two weeks. We will take completion of the questionnaire as implied consent to take part. If you return a blank questionnaire to us we will take it that you do not wish to participate in the study and we will not contact you about it again.

What happens to the results of the Feasibility Study?

The results of the Feasibility Study will be used by the research team to assess the numbers of dental practices willing, and able, to participate in the FiCTION Trial. This information will also go into a report to the NIHR HTA who have funded this study. A decision will then be made as to whether the FiCTION Trial should be run and if so what changes, if any, are needed to its design and conduct. All study data are anonymised. Participating in the Feasibility Study does not signify a commitment to take part in the FiCTION Trial. If you take part in the Recruitment Feasibility Study and are eligible and willing to take part in the FiCTION Trial, we will contact you again a short while before it starts to ask you if you would like to participate in it.

Who is organising and funding the FiCTION study?

This study has been funded by the NIHR Health Technology Assessment (HTA) programme (http://www.ncchta.org). It is being run by a team of researchers based in Dundee, Newcastle upon Tyne, Sheffield, Leeds, Cardiff and London and in a number of different dentists across the country.

Who has said that you can do the study?

FiCTION has been given a favourable opinion by the Tayside Committee on Medical Research Ethics.

What if I have any more questions?

If you have any other questions you can call up the study team in Dundee or Newcastle. All the contact details are below.

Name	Number
Clinical leads	
Dundee: Dr Nicola Innes, University of Dundee	01382 425 760
Sheffield: Professor Chris Deery, University of Sheffield	0114 271 7885
Newcastle: Dr Anne Maguire, Newcastle University	0191 222 8564
Newcastle Clinical Trials Unit	
Chris Speed	0191 222 6054
Dawn Greene	0191 222 3819

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

FiCTION TRIAL

Managing Decay for Children

Filling Children's Teeth: Indicated or Not?

FiCTION Service Providers' Focus Group

Information Sheet

We are asking you to give consent to take part in the FiCTION service providers' focus group. Before you decide about taking part it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with colleagues if you wish.

What is the FiCTION service providers' focus group?

When you agreed to take part in the pilot rehearsal trial we explained that we would like some of the participating practices and members of staff to take part in focus groups to help us fully explore the experiences of participation in the planned main FiCTION trial.

Why have you asked me to take part?

Your practice took part in the FiCTION rehearsal pilot trial therefore you are eligible to take part in the focus groups. Participation is entirely voluntary.

What will happen if I agree take part?

First, you will be contacted by a researcher and they will invite you to come along to a focus group at a time which is convenient to you. Before the focus group begins we will ask you to sign a consent form to say that you are happy to take part.

What happens at the focus group?

Pilot trial dentists and other members of the practice team will be brought together to ask about your experiences in the Pilot Trial, improvements to the design and conduct of the study for the main trial and also to explore strategies to promote retention of practices within the study.

We will tape record and transcribe the focus groups. Anything said in the groups will be anonymised and anything you say at any stage or any information you give us will be strictly in confidence.

Are there any possible benefits of taking part?

There may be no direct benefit from you taking part in the focus group. However, these groups will help us make decisions about how best to run the main FiCTION trial. This, in turn, will help us address very important questions about managing the carious primary dentition in the younger child.

What happens to the results of the focus groups?

The anonymised results of the focus groups will be circulated round the researchers working on FiCTION. We will be able to use this information to help us make any changes to the main FICTION trial before it starts. In doing this we will be able to run the best quality research we can.

The results of the focus groups will also go into a report we send back to the NIHR HTA who have funded this study. They will then decide whether the main FiCTION trial should be run. The results of the focus groups may be printed in relevant journals. The findings may also be presented at conferences where they can be shared with other dentists, healthcare professionals and researchers.

Who is organising and funding the study?

This study has been funded by the NIHR Health Technology Assessment (HTA) programme (http://www.ncchta.org). It is being run by a team of researchers based in Dundee, Newcastle upon Tyne, Sheffield, Leeds, Cardiff and London and in a number of different dentists across the country.

Who has said that you can do the study?

This research has been given a favourable opinion by the Tayside NHS Research Ethics Committee.

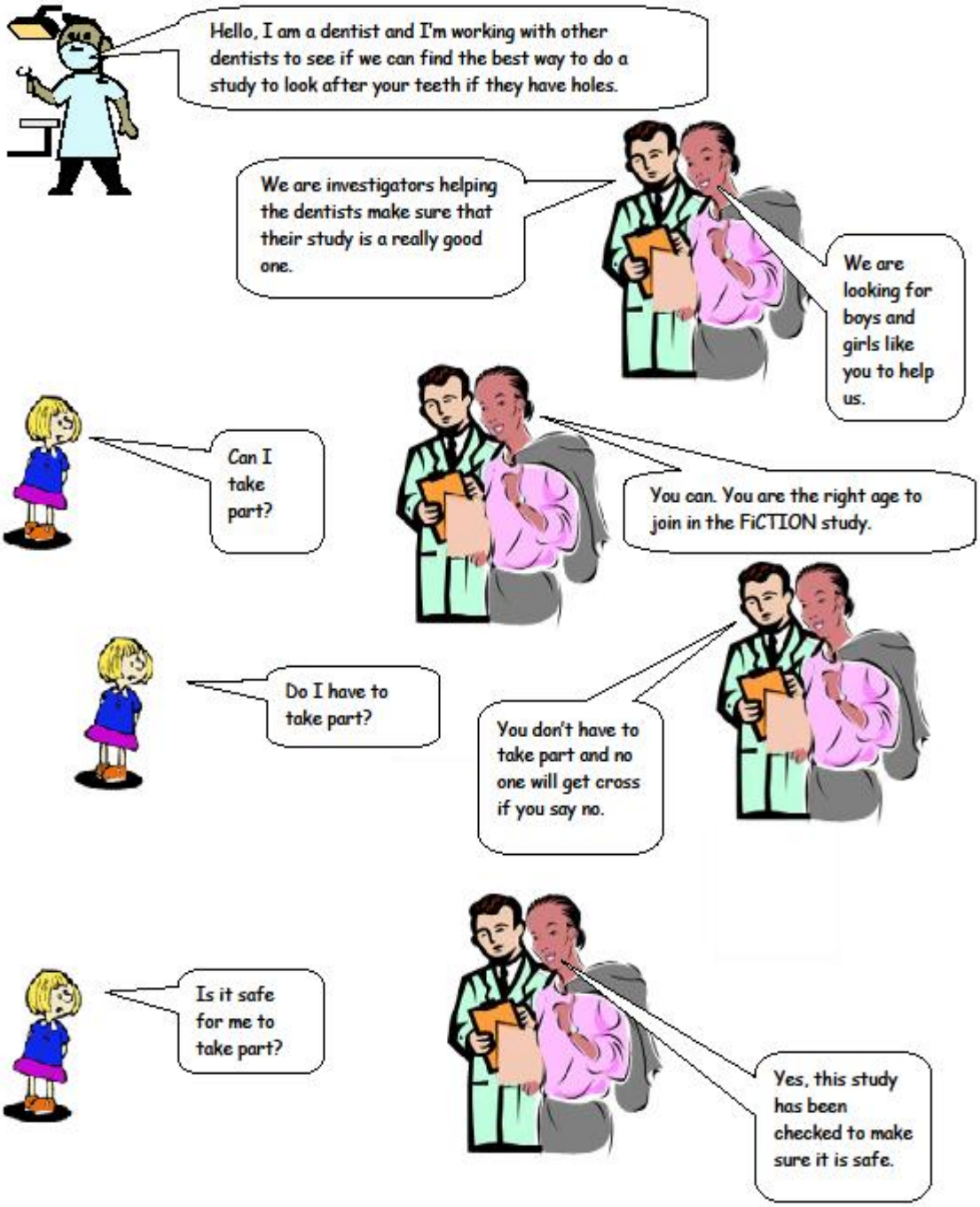
What if I have any more questions?

If you have any other questions you can call up your local clinical lead or the study team in Sheffield. All the contact details are below.

Name	Number
Clinical leads	
Dundee: Dr Nicola Innes, University of Dundee	01382 425 760
Sheffield: Professor Chris Deery, University of Sheffield	0114 271 7885
Newcastle: Dr Anne Maguire, Newcastle University	0191 222 8564
Focus Group Lead	
Dr Zoe Marshman, University of Sheffield	0114 271 7893

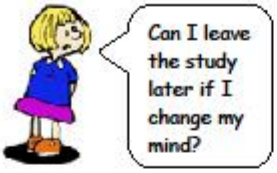
Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

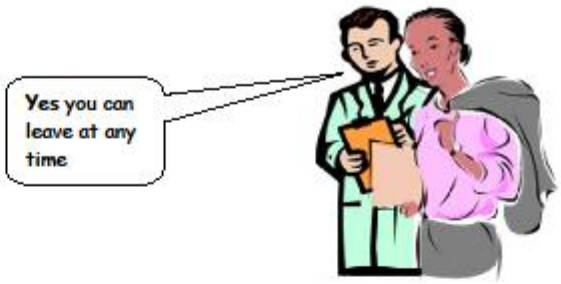
(University of Sheffield paper)
FiCTION Focus Group
Patient information sheet for children

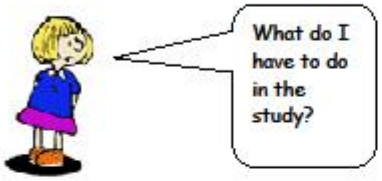


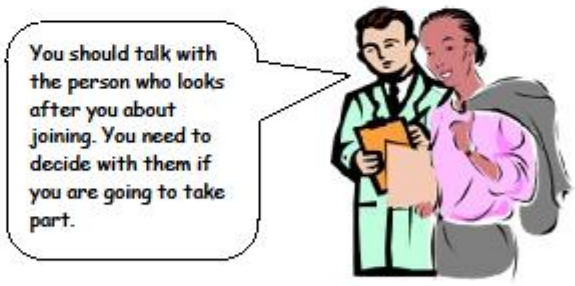
FiCTION Focus Group
Child's information sheet

Version 1.0
25/10/2010









If you have any more questions about this study you can ask your dentist.

The person in charge of the study is Zoe and her telephone number is 0114 271 7893.

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

FiCTION TRIAL

Managing Decay for Children

Filling Children's Teeth: Indicated or Not?
FiCTION Focus Group
Parent information sheet

We invite you to participate in a research project. We believe it to be of potential importance. However, before you decide whether or not you wish to participate, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Read it carefully and be sure to ask any questions you have, and, if you want, discuss it with outsiders. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.
There is a separate information sheet for your child, written in child-friendly language, enclosed with this information leaflet. We suggest you decide together about taking part.

What is the FiCTION Service Users' Focus Group?

As you may recall your dentist has been taking part in the FiCTION Pilot Rehearsal trial. They may have approached you to take part in it. The Pilot Rehearsal Trial was a 'test run' of a large study (main FiCTION trial) that we would like to start in the near future.

However, before we can run the large trial we'd like to make sure that it will be the best study it possibly can be. To do this we would like to work with people like you and your child to hear your views and opinions.

Why have you asked me and my child to take part?

We are contacting you because your dentist has approached you about taking part in the FiCTION Pilot Rehearsal Trial and you have returned a contact slip to the study team saying that we could get in touch with you.

Do we have to take part?

No, it is up to you and your child to decide whether or not they take part. They will continue to get the best possible care no matter what you decide to do.

What will happen if I agree we will take part?

First, you will be contacted by a researcher and they will invite you to come along to a focus group at a time which is convenient to you. Before the focus group begins we will ask you to sign a consent form to say that you are happy for you and your child to take part.

What happens at the focus group?

In the focus group there will be 5 adults and 5 children. It will be run by a very experienced researcher. The session should last for no more than 90 minutes and there will only be one focus group session.

We tape record the focus group so we can keep an accurate record of what is said. Anything you say in the group will be anonymised and anything you say at any stage including any information you give us will be strictly in confidence.

In the focus group we will be interested in finding out what you and your child think about the three treatment methods we hope to use in the main FiCTION trial. We would also be interested to hear what you each think about the information sheets and questionnaires we hope to use in the main FiCTION trial. We would welcome your views on how we could best promote the main FiCTION trial too.

Are there any possible benefits of taking part?

There may be no direct benefit from you taking part in the focus group. However, this group will help us make decisions about how best to run the main FiCTION trial. This, in turn, will help us address very important questions about how best to look after children's teeth.

What happens to the results of the focus group?

The anonymised results of the focus group will be circulated round the researchers working on FiCTION. We will be able to use this information to help us make any changes to the main FICTION trial before it starts. In doing this we will be able to run the best quality research we can.

The results of the focus group will also go into a report we send back to the National Institute for Health Research Health Technology Assessment (NIHR HTA) who have funded this study. They will then decide whether the main FiCTION trial should be run. The results of the focus group may be printed in dental journals, which are read by dentists and their staff. The findings may also be presented at conferences where they can be shared with other dentists, healthcare professionals and researchers. No names of participants will appear in any reports about the study. All study data are anonymised – this means that your personal details and those of your child do not appear.
We will keep the original recording of the focus group discussion for a maximum of 2 years following transcription, and we will keep the transcription for 7 years. Both the recording and the transcription are stored securely with access restricted to the research team.

Will anyone else know we are in the focus group?

We will keep you and your child's details and study information in confidence. Only key people who have a need or right to know will know you are in the study.

The study is being overseen by the Newcastle Clinical Trials Unit (NCTU) which is part of Newcastle University. Authorised people from the NCTU will look at the data collected from the study. The study data may also be looked at by the group moderator and authorised people from Dundee University as they are responsible for the research.

Who is organising and funding the study?

This research has been funded by the NIHR HTA programme (http://www.ncchta.org). It is being run by a team of researchers based in Dundee, Newcastle upon Tyne, Sheffield, Leeds, Cardiff and London and in a number of different dental practices across the country.

Who has said that you can do the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the Tayside Committee on Medical Research Ethics.

What if I have any more questions?

If you have any other questions you can call up the study team in Sheffield. The contact details are below.

Name	Number
Dr Zoe Marshman	0114 271 7893

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

FiCTION Service Providers' Focus group

Participant identification number:

Consent form

	Please put your initials in the boxes if you agree:
1. I have read and understand the FiCTION Feasibility Service Provider's Study information sheet version 1.0 dated 25th October 2010 and have had the opportunity to ask questions.	
2. I understand that I do not have to take part in the FiCTION Feasibility Service Provider's Study. I also understand that I can opt out at any time, without giving a reason.	
3. I understand that the anonymised data collected during the study, may be looked at by responsible individuals from the study team and from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have these data.	
4. I agree to take part in the FiCTION Feasibility Service Provider's Study.	
5. I agree to the information provided in this study being managed by the Newcastle Clinical Trials Unit.	

Name of participant **(Please PRINT name and give title eg Dr, Mr/Mrs/Ms/Miss)**	Date	Signature
Name of person taking consent	Date	Signature

(1 for participant, 1 for research team)

FiCTION Focus Group

Patient identification number:

Adult Consent form

	Please put your initials in the boxes if you agree:
1. I have read and understand the FiCTION Focus Group Information Sheet version 1.0 dated 25th October 2010 and have had the opportunity to ask questions.	
2. I understand that I do not have to take part in the FiCTION Feasibility Study. I also understand that I can opt out at any time, without giving a reason, and without this affecting our dental care or legal rights.	
3. I understand that the anonymous data collected during the study, may be looked at by responsible individuals from the study team and from regulatory authorities or from the NHS Trust (England) or NHS Tayside, where it is relevant to my child taking part in this research. I give permission for these individuals to have these data.	
4. I agree to being included in the FiCTION Focus Group.	
5. I agree to the information provided in this study being managed by the Newcastle Clinical Trials Unit.	

Name of parent **(Please PRINT name and give title eg Mr/Mrs/Ms/Miss)**	Date	Signature
Name of person taking consent	Date	Signature

(1 for patient, 1 for research team)

FiCTION Focus Group

Patient identification number:

☐☐ ☐☐ ☐☐☐

Assent form

	Please put a circle round the one you agree with:
1. Have you read (or had read to you) about this study?	Yes / No
2. Has somebody else explained this study to you?	Yes / No
3. Do you understand what this study is about?	Yes / No
4. Have you asked all the questions you want?	Yes / No
5. Have you had your questions answered in a way you understand?	Yes / No
6. Do you understand it's OK to stop taking part at any time?	Yes / No
7. Are you happy to take part?	Yes / No

If you do want to take part, you can write your name below.

If any answers are 'no' or you don't want to take part, don't sign your name!

Name of child (please PRINT name)	Date	Child to write name here
Name of person taking consent	Date	Signature

(1 for patient, 1 for research team)

FiCTION Focus Group

Patient identification number:

Parent Consent Form
(to be filled in on behalf of the child)

	Please put your initials in the boxes if you agree:
1. I have read and understand the FiCTION Focus Group Information Sheet version 1.0 dated 25th October 2010 and have had the opportunity to ask questions.	
2. I understand that my child does not have to take part in the FiCTION Feasibility Study. I also understand that s/he can opt out at any time, without giving a reason, and without this affecting our dental care or legal rights.	
3. I understand that the anonymous data collected during the study, may be looked at by responsible individuals from the study team and from regulatory authorities or from the NHS Trust (England) or NHS Tayside, where it is relevant to my child taking part in this research. I give permission for these individuals to have these data.	
4. I agree to my child being included in the FiCTION Focus Group.	
5. I agree to the information provided in this study being managed by the Newcastle Clinical Trials Unit.	

Name of parent **(Please PRINT name and give title eg Mr/Mrs/Ms/Miss)**	Date	Signature
Name of person taking consent	Date	Signature

(1 for patient, 1 for research team)

18.1. QUESTIONNAIRES

db	cc	pv	va

CONFIDENTIAL

Area		Site		Participant			
				3			

FiCTION TRIAL

Managing Decay for Children

Questions about the practice

Newcastle Clinical Trials Unit
Institute of Health and Society
4th Floor, William Leech Building
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

☎ 0191 222 6054 / 3819

ISRCTN77044005

About these questions

In this booklet, you will find some questions about your dental practice. The responses to these questions will help us to assess ability to take part in the FiCTION Main Study.

Although we may contact you about FiCTION in the future, filling in this questionnaire **does not** mean that you have to take part in the FiCTION Main Trial.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are left handed.

Are you

Right handed 1

Left handed ..... (2)

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1965

What is your date of birth?

1	9		0	4		6	5
day			month			year	

Please answer **every question**, unless the instructions tell you to do something else.

If you have problems answering any question, please write that problem beside the question.

Remember that your responses will remain confidential.

Please now go to the next page

The following questions ask about your practice and its facilities.

In order to take part in the FiCTION Main Trial practices need to be able to perform an age - range search on their database for possible participants (children aged between 3 and 7 years old). They also need to have access to the internet in order to use the randomisation system for the study.

In addition, digital technology for radiographs is preferred for ease of use, although analogue will be considered as a possibility.

In order to assess a practice's ability to participate in the trial therefore it would be very helpful if you could fill in the following questions.

1) Does your practice use a computerised clinical database system (patient management system)?

Yes .....1 **Go to Question 2**

No .....2 **Go to Question 3** 9

2) What is the name of the system your practice uses?

..... ☐☐ 11

3) How confident are you that your practice can search practice records for children aged between 3 and 7 years old? *(Please circle the number that best applies)*

Confident 1

Not confident 2 12

4) How many children aged between 3 and 7 years old are on your practice records? *(please write the number in the box below or leave blank if you are unable to provide this information at this time)*

☐☐☐ 15

5) What technology is available in the practice for taking radiographs? (*Please circle all numbers that apply*)

Analogue 1

Digital 2 17

6) Does your practice have internet access which is readily available to you? (*Please circle the number that best applies*)

Yes 1

No 2 18

7) Is there a room available in the practice for the completion of study documentation (questionnaires) by participants?

Yes 1

No 2 19

8) Please tell us the role/job title of the person completing this questionnaire:

..... ☐☐ 21

Thank you very much for filling in this questionnaire.

Please check that you have answered all the questions in this booklet. When you have finished please return the booklet to us in the envelope provided. No stamps are needed.

If you want to ask anything about the study then please feel free to contact the research team – our contact details are shown below.

Name	Organisation	Tel.	Email
Mr. Chris Speed	Newcastle Clinical Trials Unit	0191 222 6054	chris.speed@ncl.ac.uk
Mrs. Dawn Greene	Newcastle Clinical Trials Unit	0191 222 3819	dawn.greene@ncl.ac.uk

db	cc	pv	va

CONFIDENTIAL

Area		Site		Participant			
				3			

FiCTION TRIAL

Managing Decay for Children

Questions and case study about clinical decisions

Newcastle Clinical Trials Unit
Institute of Health and Society
4th Floor, William Leech Building
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

☎ 0191 222 6054 / 3819

ISRCTN77044005

Clinical decisions and equipoise V1.0 25/10/10

About these questions

In this booklet, you will find some questions about clinical decisions.

Filling in this questionnaire **does not** mean that you have to take part in the FiCTION Main Trial.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are left handed.

Are you

Right handed..... 1

Left handed ..... (2)

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1965

What is your date of birth?

1	9		0	4		6	5
day			month			year	

Please answer **every question**, unless the instructions tell you to do something else.

If you have problems answering any question, please write that problem beside the question.

Remember that your responses will remain confidential.

Please now go to the next page

1) This question asks about how willing you would be to deliver an intervention selected at random as part of a clinical trial.

We are preparing to conduct a clinical trial which investigates the best way to manage dental caries in young children. The trial will recruit children between 3 and 7 years of age with decay into dentine in one primary molar. Their teeth will be symptom-free and have no other signs of infection.

There is evidence to support the three interventions we are trialling. However, the definitive answer as to the most clinically and cost effective is yet to be found.

We understand that often dentists have a preference for a particular technique for managing caries. As part of the preparatory work we need to assess whether dentists' would be open to following a randomly selected treatment strategy during the trial even if it was not the approach they would routinely use.

The three treatment strategies we are using in the clinical trial are:

Surgical management of decay with prevention
Surgical management is conventional, restorative, paediatric dentistry.

Biological management of decay prevention
In this treatment the caries is sealed from the oral cavity by application of an adhesive material, or a metal crown. Decay is, on occasion, removed prior to the tooth being sealed. No injections are needed. Creating a 'self-cleansing' cavity is a possible technique within this strategy.

Prevention alone
With good oral hygiene and additional fluoride application it is possible to slow down the rate of caries progression. For the best practice prevention alone arm, no drilling, filling or sealing of teeth will occur. Dentists will provide best practice prevention

As part of the trial you will be fully trained to deliver all of the intervention techniques.

The Case Study Scenario

A child between 3 and 7 years of age with decay into dentine in one primary molar presents at the practice.

Their teeth are symptom-free and have no other signs of infection.

a) Would you be open to use one of these approaches if it was randomly allocated?

Yes .....1 (go to question 2)

No.....2 (please answer part b)

9

b) If you answered 'no', please tell us why?

.....

..... (go to question 2)

☐☐☐ 12

Please continue with question 2 on the following page

2

2) Thinking about the three treatment approaches described above

a) How certain are you that strategy 1 (Surgical management of decay, with prevention) is an appropriate intervention in this case? *Please circle the number that best applies to you.*

Certain	.....	1
Not certain	.....	2

13

b) How certain are you that strategy 2 (Biological management of decay, with prevention) is an appropriate intervention in this case? *Please circle the number that best applies to you.*

Certain	.....	1
Not certain	.....	2

14

a) How certain are you that strategy 3 (Prevention alone) is an appropriate intervention in this case? *Please circle the number that best applies to you.*

Certain	.....	1
Not certain	.....	2

15

3) Would you like us to contact you about taking part in the FiCTION trial in the future?

Yes	.....	1
No	.....	2

16

Thank you very much for filling in this questionnaire.

Please check that you have answered all the questions in this booklet. When you have finished please return the booklet to us in the envelope provided. No stamps are needed.

If you want to ask anything about the study then please feel free to contact the research team – our contact details are shown below.

If you have said that you would like us to contact you about the FiCTION trial we will do so at a later date.

Name	Organisation	Tel.	Email
Mr. Chris Speed	Newcastle Clinical Trials Unit	0191 222 6054	chris.speed@ncl.ac.uk
Mrs. Dawn Greene	Newcastle Clinical Trials Unit	0191 222 3819	dawn.greene@ncl.ac.uk

3

FiCTION Pilot Rehearsal Trial

FiCTION Pilot Rehearsal Trial

Filling Children's Teeth: Indicated or Not? Pilot Rehearsal Trial

Protocol ID: NCTU:ISRCTN77044005

ISRCTN77044005

Protocol Version 1.1

Date: 14/12/09

Funded by the NIHR HTA

1 PROTOCOL CONTACTS

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DD1 4HN
UK

Chief Investigator:
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Co Investigator:
Professor Jan Clarkson
Programme Director, Consultant in Paediatric Dentistry
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2 PROTOCOL SIGNATURE PAGE

2.1 PROTOCOL AUTHORISATION SIGNATORIES

Signature ……. Date…….
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Dr Nick Steen Statistician

Signature ……. Date…….
Dr Mark Deverill Health Economist

Signature ……. Date…….
Mr Chris Speed, Senior Trial Manager

Principal Investigator Signature

I confirm that I have read and understood protocol version 1.0 dated (date). I agree to comply with the study protocol, the principles of GCP and the appropriate reporting requirements.

Signature ……. Date…….

Print Name ……

Site Name/I.D. ……

3 CONTENTS

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3.1 FIGURES

4 GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
DMEC	Data Monitoring & Ethics Committee
GCP	Good Clinical Practice
MCDAS	Modified Child Dental Anxiety Scale
MREC	Main Research Ethics Committee
NCTU	Newcastle Clinical Trials Unit
P-CPQ	Parental-Caregivers Perceptions Questionnaire
PI	Principal Investigator (at each site)
QOL	Quality of Life
R&D	Research and Development
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse reaction
TSC	Trial Steering Committee
VAS	Visual Analogue Scale

KEYWORDS

Caries prevention, primary teeth, prevention, paediatric dentistry, restoration, fillings, RCT, primary care.

5 RESPONSIBILITIES

Sponsor: University of Dundee

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
1. Study preparation	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor	
	b) Secure and administer funding for the Study.	Sponsor	Chief Investigator
	c) Secure and contract for the supply of resources including medicinal products/devices/CRO services.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor	
2. Applications and Registration	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor	
	b) Prepare Participant information sheet and consent form, including where appropriate consent to providing Participant tissue, sample, medical data or other material to the Sponsor and other relevant documents prior to ethics submission.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Prepare and submit ethics application.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Register the Study with an appropriate protocol registration scheme.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Obtain NHS permission.	Sponsor	PI at site
3. Protocol Amendments	a) Prepare and submit proposed substantial amendments of the Protocol to the regulatory authority(ies), relevant ethics committee and NHS Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
4. Study Conduct	a) Ensure that legislation in relation to research is followed within the Site	Sponsor	PI at site
	b) Ensure that the Study Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	c) Ensure that no Participant is recruited until a favourable ethical opinion has been provided	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and Clause 2 of this Agreement	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol.	Sponsor	Chief Investigator / Newcastle Clinical Trials
	g) Ensure that the rights of individual Participants are protected and that they receive appropriate dental care whilst participating in the Study.	Sponsor	PI at site
	h) Maintain and archive Study documentation at the Site.	Sponsor	PI at site
	i) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant.	Sponsor	PI at site
	j) Inform appropriate health or social care professionals if their patient is a Participant in the Study in accordance with the Research Governance Framework.	Chief Investigator	PI at site

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
	k) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit & PI at site
	l) Report suspected research misconduct.	Sponsor	Chief Investigator
	m) Notify the regulatory authority(ies) of the end of the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	n) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
5. Adverse events	a) Maintain detailed records of all adverse events as specified in the Protocol.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Report adverse events as agreed in the Protocol and to legal requirements and in accordance with Trust policy.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Promptly inform regulatory authorities, ethics committees and investigators of any urgent safety measures taken to protect Participants in the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that annual safety reports and end of Study reports are generated and submitted to the regulatory authority and relevant ethics committee within the required timeframes.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
6. Data Management	a) Design of case report forms and database.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure appropriate analysis of data.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
7. Publication	a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
8. Archiving	a) Ensure that all Study records are archived appropriately on conclusion of the Study and retained for seven (7) years	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
9. Clinical Trials	a) Ensure that the Study is conducted in accordance with the principles of Good Clinical Practice (GCP).	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure that all Serious Adverse Events (SAE), other that those specified in the Protocol as not requiring immediate reporting, are promptly assessed as regards the requirement for expedited reporting to the regulatory authority and relevant ethics committee.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of trial safety.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are identified and fully reported to the relevant ethics committee within the required timelines.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Ensure that investigators are aware of any SUSARs occurring in relation to the interventions.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

6 PROTOCOL SUMMARY

Full Title:	Filling Children's Teeth: Indicated or Not? Pilot Rehearsal Trial
Short title:	Short Title: FiCTION Pilot Rehearsal Trial
Protocol version:	1.1
Protocol date:	14/12/09
Chief Investigator:	Nicola Innes
Sponsor:	University of Dundee
Funder:	NIHR HTA
Study design:	A Pilot Rehearsal Trial rehearsal trial of the proposed multi-centre, three-arm parallel group, patient randomised, FiCTION trial
Study intervention:	Arm 1 - Surgical management of decay, with best practice prevention Arm 2 - Biological management of decay, with best practice prevention Arm 3 - No fillings, best practice prevention alone
Study objectives:	To inform the decision of whether to proceed to the full FiCTION trial and whether any refinements to the design or conduct of that trial are warranted.
Study outcome:	The confirmation or otherwise that practices are able to identify the required number of eligible children and recruit them. The acceptability of the treatment strategies (as manifested through recruitment and retention levels), the feasibility and acceptability of the data collection tools (completion rates and quality of data) and clinical data to confirm or adjust the sample size for the FiCTION trial.
Study sites:	Dental practices in Scotland (n=3), Newcastle (n=5), Sheffield (n=3)
Study population: decay into dentine	Children aged 3 - 7 years of age with at least one primary molar tooth with
Study duration:	15 months

7 INTRODUCTION

7.1 BACKGROUND

The lack of evidence for the effective management of dental decay in children's primary teeth is causing considerable uncertainty for the dental profession and patients. In particular, the apparent failure of conventional dental fillings to prevent pain and sepsis for UK children in primary care [1] has prompted much debate. At the present time, teaching in UK dental schools is based on guidance from the British Society of Paediatric Dentistry (BSPD) which includes the recommendation that the optimum treatment of decay in primary teeth should be its removal, followed by the placement of a conventional filling to replace lost tooth tissue [2, 3]. However, these recommendations are largely based on evidence for the effectiveness of fillings obtained from studies conducted in either a secondary care or specialist paediatric practice setting. While both the volume and quality of the research on which the guidance is based is limited, it is acknowledged that fillings provided in specialist clinical environments can be effective [4]. It is the generalisability of this evidence to a primary care setting which is in question, and in particular the barriers, e.g. time, to providing fillings of sufficient quality to prevent pain and sepsis.

In the UK, the majority of dental care for children is provided in primary care by general dental practitioners (GDPs). Three recent studies, conducted in general dental practice in the UK, have provoked the current debate of what is appropriate and effective care for children with decay in primary teeth. The first of these was a retrospective case note study, based on a group of 50 GDPs' patient records, which suggested that placing a filling compared with leaving the tooth unfilled did not improve the clinical outcome in terms of dental pain and sepsis [1]. In fact, the likelihood of children with filled teeth experiencing dental pain or sepsis was similar to that reported for the second study of 481 children who attended two general dental practices with a practice policy of leaving asymptomatic carious primary teeth unrestored, focussing on a preventive strategy alone to manage them [5]. The third, and most recent, was a randomised controlled trial involving 18 GDPs and, arguably, provides the most robust evidence. The results demonstrate the ineffectiveness of the conventional, surgical approach (that is drilling out decay and placing a filling) to treating decay in general dental practice. This trial showed a failure rate in terms of pain and sepsis, after two years, approaching that reported by the previous two studies for unrestored teeth [6].

Perhaps because of perceived ineffectiveness, the traditional "drill and fill" methods of managing decayed primary teeth are not popular with GDPs [7]. Less than 10% of decayed teeth in 5 year-old children are currently filled [8]. However, a recent Cochrane review [9] found that emerging biologically-orientated strategies for managing decay (sealing some of the decay within the tooth rather than drilling it all out) are effective. In addition, a "biological" method of managing primary teeth by sealing in the decay with preformed metal crowns (PMCs) has been found to be both effective at preventing pain and sepsis, and acceptable to children, parents and GDPs [6].

Currently GDPs in the UK are providing care for children under different funding systems. Whilst the implication of the funding systems on the type and quality of care is unknown, there is universal agreement that guidance for the effective management of decay is needed. In Scotland, the capitation and fee per item of service system is in operation, and to assist healthcare workers and patients the Scottish Dental Clinical Effectiveness Programme is currently in the process of developing national guidance for the management of decay in children. In England and Wales many Primary Care Trusts (PCTs) are now seeking to secure adherence to best practice guidance as part of their clinical governance responsibilities when commissioning dental primary care services. However, the lack of direct evidence relevant to the setting where the vast majority of child dental care is carried out, general dental practice, and the discrepancy between the evidence for restorative management of decay in the primary and secondary care settings, complicate the development of the process of care for what is the most common disease of young children. There is a gulf between the management strategies for decayed primary teeth recommended by the BSPD (and taught in UK dental schools),

and the treatment currently being provided by GDPs. As yet, there is insufficient evidence on which to base a recommendation as to which of three possible management strategies: the surgical approach (tradition fillings); the biological approach (including sealing caries to stop its progress); or prevention alone where no fillings are placed, is the most effective at managing dental decay in children in primary care. The implication of this research is likely to be a change in policy for service and education in the NHS and beyond.

7.2 RATIONALE FOR CURRENT STUDY

The definitive, multi-centre FiCTION trial will address the research question "What is the clinical and cost effectiveness of filling caries in primary teeth, compared to no treatment?" The FiCTION trial will also compare the relative clinical and cost effectiveness of the following three treatment strategies:

Surgical management of decay, with best practice prevention
Surgical management is commonly known as the 'drill and fill' method. In this treatment the tooth is numbed with a dental injection, then mechanical removal of the decay is carried out using a rotary instrument (drill) and a filling is placed in the tooth.

Biological management of decay, with best practice prevention
In this treatment arm, cavities are assessed clinically for whether the decay is active and if so, it is sealed from the oral cavity by application of an adhesive filling material, or by covering with a metal crown. Decay may, on occasion, be partially removed prior to the tooth being sealed. Injections are rarely needed.

No Fillings, best practice prevention alone
With good oral hygiene it is possible to slow down the rate of tooth decay and prevent toothache and infection of the gums with sepsis. For the best practice prevention alone arm, no drilling, filling or sealing of primary teeth will occur. Dentists and other members of the dental team will base treatment plans for patients on best practice preventive care for teeth and oral health. Fluoride varnish and fissure sealant may be applied.

The rationale for this pilot rehearsal trial is that, in advance of the definitive multi-centre FiCTION trial, it is necessary to assess whether the proposed design for the FiCTION trial is practicable and will allow the proposed outcomes to be assessed.

8 STUDY OBJECTIVES

The objective of the proposed definitive multi-centre FiCTION trial is to compare the three treatment strategies, when applied over a period of three years to 3-7 year-old children with caries in primary teeth. With respect to the outcomes, the primary clinical outcomes are incidence of pain and sepsis. The pilot rehearsal trial of the proposed methods and interventions from the FiCTION trial, in a smaller number of practices and over a shorter period, has the objective of providing data on practice ability to identify and recruit the required number of children, acceptability of the treatment strategies (as manifested through recruitment and retention levels), the feasibility and acceptability of the data collection tools (completion rates and quality of data) and clinical data to confirm or adjust the sample size for the trial.

Ultimately, the results of the pilot rehearsal trial in addition to the parallel feasibility study (Protocol ID NCTU:FS77044005) will inform the decision of whether to proceed to the full trial and whether any refinements to the design or conduct of that trial are warranted.

9 STUDY DESIGN

A sample of children (n=741) between the ages of 3 and 7 years old will be identified across dental practices participating in the pilot rehearsal trial. Practices will be asked to carry out simple searches on their practice databases in order to identify potentially eligible children using a date of birth query. Potentially eligible children due for a recall appointment will be invited to participate by letter of invitation from the child's GDP. This letter, along with an information sheet for parents and an information sheet for the child will be sent along with their dental appointment card at least one week in advance of the scheduled recall appointment.

All potentially eligible children will be screened for entry to the pilot rehearsal trial at routine recall appointments with their dentist, until the practitioner has recruited 15 children.

Telephone numbers of the GDP and of the research team will be provided in case there are any questions the parents may have which are not addressed in the information sheet. At the recall/recruitment appointment, if there is evidence of caries, and absence of pain and sepsis, the child's GDP will discuss the trial with the parent and child and will answer any questions they may have. If the parent and child are willing to participate, written informed consent will be obtained from the parent and oral or written assent will be obtained from the child, prior to any study specific procedures being carried out.

For those children without evidence of caries, or where pain and/or sepsis are present the GDP will explain why it is not possible to take part in the FiCTION pilot rehearsal trial at that time. If a child is free of caries at the screening check, but then develops caries during the course of the pilot rehearsal trial they may be invited to join the study if the recruitment phase is still active. Similarly, if on a subsequent visit a child with caries presents who no longer has the pain and/or sepsis evident at the initial screening, they may be invited to join the study if the practitioner's target number of 15 recruits has not been met.

Once eligibility has been confirmed by the GDP and informed consent and assent given, participants will be given a subsequent treatment appointment, prior to which randomisation via the NCT randomisation service will be carried out. Upon attending this subsequent appointment participants will be informed as to which treatment arm has been allocated to them and will commence treatment as per protocol and the International Caries Detection and Assessment System (ICDAS) [10] assessment undertaken. Participants will be given a letter to give to their GP, informing them of their involvement in the study.

All participants will also be asked whether they would be willing to be contacted by a researcher from the trial team to discuss their reason for participation. If they are willing, they will be asked to complete a *contact details* form which will be returned to the study team.

The contact details form will also contain a question about willingness to be contacted in future to take part in a focus group exploring their experiences in the study.

Eligible participants not wishing to take part will receive their dental check up as normal. They will also be asked whether they would be willing to be contacted by a researcher from the trial team to discuss their reason for nonparticipation. If they are willing, they will be asked to complete a *contact details* form which will be returned to the study team.

The data generated by this exercise will be used to refine the protocol for the main study by identifying whether strong preferences for a particular treatment strategy played a role in the decision to participate. If this was not a factor in the non-participation group, this exercise will help to identify factors which were important to them. It will also inform the number of patients who need to be approached for the main trial and indicate the likely extent of participation bias.

The target sample size to be recruited and randomised for the pilot rehearsal trial is 200 children who meet the eligibility criteria and agree to participate (see section 10). The pilot rehearsal trial (see figure 1) will comprise simple randomisation of patients into the three caries management strategies in a 1:1:1 ratio. Randomisation will be through the web-based, automated central randomisation facility at the Newcastle Clinical Trials Unit (NCTU) using variable length random permeated blocks to ensure concealment of allocation. The intention is that patients will be managed throughout their time in the study according to the randomisation arm to which they were allocated, i.e. any subsequent episode of caries will be managed in the same way (as per random allocation) as the initial episode. Any crossover that does occur because patients or parents transfer to another arm or opt to have treatment which is part of another arm will be monitored rather than risking dropout of the patients.

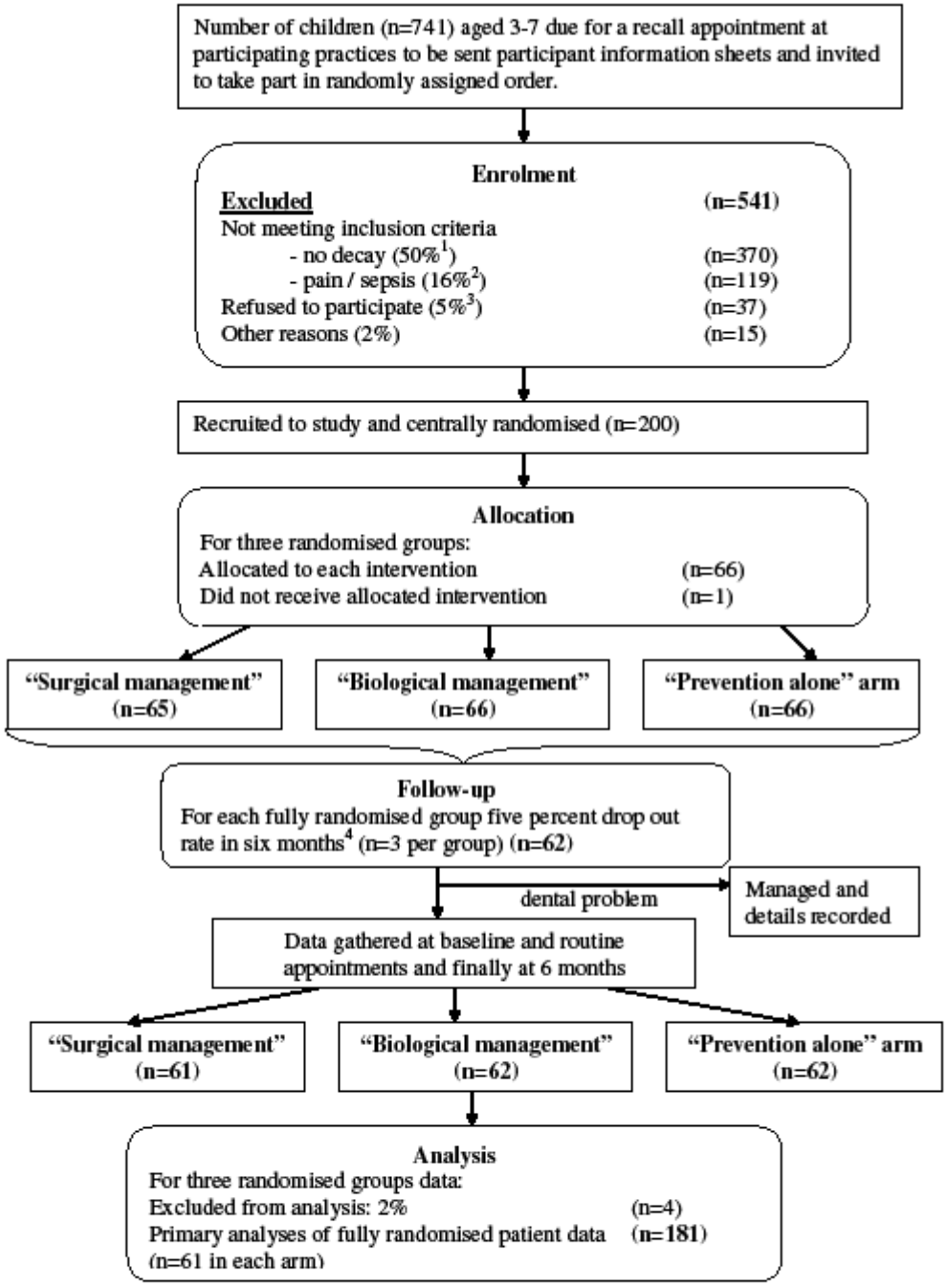
Questionnaires to explore the strength of preferences for 'surgical', 'biological' or 'prevention alone' tooth decay management strategies will be given to all randomised participants at their 6 month follow-up assessment visit. These strategies may identify any sources of bias in the recruitment process that could be avoided in the main trial.

9.1 SELECTION OF PRACTICES FOR PILOT REHEARSAL TRIAL:

A purposive sample of eleven practices (approx 18 dentists to identify 741 patients and enrol 200 patients), drawn from three of the five centres proposed for the definitive multi-centre trial will be involved in the rehearsal pilot [11]; selection of these practices will reflect the socio-demographic mix of the catchment communities. While the sample for the pilot study is purposive, in the interests of ensuring that the practices are representative, those with strong links to any of the academic centres collaborating in this study have not been included. The choice of the three geographic centres for the rehearsal pilot is based on the need to assess the impact on trial feasibility of characteristics of potential relevance to 1) working with practices and 2) the likelihood of patient recruitment. Water fluoridation (Newcastle) is associated with lower decay rates and a different clinical presentation of the disease compared with non-fluoridated areas [12]. Ethnic diversity (Sheffield) is associated with differing dental decay risk factors [13] and barriers to trial recruitment [14]. The variation in service funding and differences in NHS research support and treatment costs are reflected by including practices in Scotland (Dundee). Potential practices will be visited by the research team to assess eligibility before being invited to take part. Involving eleven practices in three different areas in the rehearsal pilot trial will allow early identification of potential hurdles to the introduction of the intervention across multiple and diverse sites. Demonstration of the ability of the research team to work with, and retain, practices will be shown through: attendance by all enrolled dentists and their nurses for training in the study protocols and outcome measures; completion of all study forms for the period of the pilot trial; and retention of the practices throughout the rehearsal pilot trial.

Demonstration of the ability of the research team to work with, and retain, practices will be shown through: attendance by all enrolled dentists and their nurses for training in the study protocols and outcome measures; completion of all study forms for the period of the pilot trial; and retention of the practices throughout the pilot rehearsal trial.

Figure 1: Flow diagram of pilot rehearsal trial



1. Using UK Child Dental Health Survey data from 2003 where 43% of children at five years old and 57% of eight years old had decay we estimate an average figure of 50% of five to seven year olds will have decay. This will be verified in the study population as will all other estimates.
2. Estimated on the basis that 16% of parents of five year olds who were regular attenders reported problems with pain (UK Child Dental Health Survey. 2003)
3. Estimated from research team's previous clinical trials.
4. Estimated from first year drop out rates in research team's experience with previous clinical trials in primary care.

10 STUDY OUTCOME MEASURES

10.1 DATA COMPLETION RATES:

One outcome measure from the pilot rehearsal trial will be data completion rates (see section 12 for details of the data collection tools used). Data completion rates will be used to guide us in our choice and mode of administration of questionnaires and data collection tools for the main FiCTION trial.

10.2 RECRUITMENT & RETENTION LEVEL:

Another key outcome will be recruitment, the proportion of those children who agree to be randomised to the three treatment strategies, and retention (a retention rate at six months of less than 90% will be regarded as unacceptable). The pilot rehearsal trial study will also allow us to check and, if necessary, refine, our assumptions regarding rates of eligibility and willingness to participate. We currently estimate (Figure 1) that 50% of children attending for routine review appointments will be ineligible because they do not have decay extending into the dentine in at least one primary molar tooth, that a further 16% of all presenters (32% of those with decay) will have pain or sepsis associated with their decay and will therefore be ineligible, that 5% of all children/parents (15% of those eligible because they have decay but no pain or sepsis) will be unwilling to participate and that a further 2% of all identified children will be excluded for other reasons. If the upper 95% confidence limit for the observed retention rate at 6 months is less than 90% we will regard this as evidence that the rate is unsatisfactory with negative implications for the external validity of the full trial. If we recruit 200 children to the trial the observed retention rate must be at least 85% to meet this condition.

11 PARTICIPANT ENTRY

11.1 INCLUSION CRITERIA

Child patients (3-7 years of age), male and female, who:

1. are willing to be examined
2. have at least one primary molar tooth with decay into dentine

11.2 EXCLUSION CRITERIA

1. patients who are accompanied by an adult who lacks the legal or mental capacity to give informed consent
2. patients who, at the recruitment appointment, present with either toothache or sepsis (as diagnosed by the GDP from patient history, examination, radiographs) associated with dental caries. These patients will not be enrolled into the study at this point, but after treatment may be reassessed for eligibility. *Discomfort associated with erupting teeth/exfoliating teeth,an incident of trauma or oral ulceration is not an exclusion criterion*.
3. patients with a medical condition requiring special considerations with their dental management, e.g. cardiac defects, blood dyscrasias.
4. patients currently involved in any other research which may impact upon this study.
5. patients who will move out of the catchment area for the dental practice during the 6 months following recruitment.

11.3 WITHDRAWAL CRITERIA

There are two withdrawal options:

1. Withdrawing completely (i.e. withdrawal from both the study treatment and provision of follow-up data)
2. Withdrawing partially (i.e. withdrawal from study treatment [including a request to move to another treatment arm] but continuing to provide follow-up data by attending clinic and completing questionnaires).

Consent will be sought from participants choosing option 1 to retain data collected up to the point of withdrawal. Participants will be asked if they would be happy for the reason for the decision to withdraw to be recorded. This information will be used to refine the protocol for the main study.

12 ADVERSE EVENTS

12.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

12.2 EXPECTED ADVERSE EVENTS OR REACTIONS TO TREATMENT

Whilst it is anticipated that the incidents of serious adverse events and reactions to the treatments are rare it is understood that there are a number or common and well understood consequences of the treatments in the FiCTION pilot rehearsal trial. A full listing of the common & well understood consequences of treatment, less common side effects and rare events can be found in appendix 2.

12.3 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

12.4 NON SERIOUS ADVERSE EVENTS

All such events, whether expected or not, should be recorded.

12.5 SERIOUS ADVERSE EVENTS

All Serious Adverse Events shall be reported to the Newcastle Clinical Trial's Unit within 24 hours of the PI learning of its occurrence by using the eSAE CRF facility available in the Symphony Software. A secure fax line will also be available to send a paper-based SAE CRF in the event of a software failure.

The initial report should contain the following minimum information*:

1. Study identifier (Protocol number)
2. Participant's unique study number
3. Date of birth
4. Event description
5. Start date of event
6. Reason for seriousness (i.e. death, life-threatening, hospitalisation, disability/incapacity or other)
7. Reporters name, signature & date

*In the case of incomplete information at the time of the initial reporting, all appropriate information should be provided as follow-up as soon as it becomes available.

Hospitalisations for elective treatment of a pre-existing condition do **not** need reporting as SAEs. Unrelated hospitalisations will be elicited at the follow up appointment, scheduled subsequent appointments and all emergency appointments.

All SAEs should be reported to the MREC where in the opinion of the Chief Investigator, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and
- 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence (see 11.1.1)

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies.

Local investigators should report any SAEs as required by their Local Research Ethics Committee and/or Research & Development Office.

Contact details for reporting SAEs
Fax: 0191 222 8901, attention NCTU FiCTION Trial Manager

13 ASSESSMENT AND FOLLOW-UP

All potential participants will have a routine screening examination to confirm eligibility. This screening will consist of standard dental recall clinical investigations (questioning regarding oral pain since last visit, current oral pain, clinical examination of the soft tissues and teeth, radiographs in line with national guidance) and standard dental recall medical checks. This will allow identification of children with dental caries and will also allow children with current pain or sepsis and medically compromised children to be excluded from the study.

Eligible children will then be consented and have a detailed baseline dental examination (see appendix 1 for details of the pilot rehearsal trial investigations and assessments). For children where consent is not given for participation in the trial, the dentist will carry out their normal dental care.

13.1 PAIN AND SEPSIS

Assessments for pain and sepsis will be made at each visit throughout the patient's participation in the trial. Pain resulting from toothache / other oral pains will be assessed using the Dental Discomfort Questionnaire (DDQ8) and will be completed by the parents. Discomfort during dental treatment, will be assessed using a Visual Analogue Scale (VAS – completed by the child). The DDQ8 has been shown to be a valid and reliable measure of toothache in young children (in a sample with a mean age of 4 years) and may be abbreviated to just 8 items (DDQ8) [15]. The DDQ8 is completed by parents and is therefore a proxy measure of pain/discomfort through observations of the child's behaviour. VASs are often used with children to assess self-report of such measures as fear or pain and can be used from a very young age with acceptable levels of reliability [16]. At the end of each appointment the child will be given a faces VAS to report on their levels of pain in relation to that particular visit. In addition, parents will also be asked to report on their perceptions of their child's levels of pain regarding that particular visit to the dentist. In order to differentiate between pain originating from a decayed tooth and pain from other causes, the dentist will form a diagnosis based on patient/parent history and the clinical evidence available from examination.

13.2 DENTAL DECAY

Measurements of caries experience will be made using the ICDAS [10]. This will be completed at the initial treatment appointment by the participating GDPs, who will be trained in its use. The caries detection elements of the ICDAS criteria are now well tested for use in the clinical trial arena and in dental epidemiology [10]. The ICDAS criteria measure both early and more advanced stages of caries. For early caries, ICDAS measures the surface changes and potential histological depth of carious lesions by relying on surface characteristics related to the optical properties of sound and demineralised enamel prior to cavitation. The primary requirement for applying the ICDAS system is the examination of clean and dry teeth aided when necessary by a ball-ended explorer that is used to remove any remaining plaque and debris and to check for surface contour, minor cavitation or sealants. All surfaces of all teeth will be examined and the status of each recorded in terms of caries and restorations. This system allows the recording of both preventive and operative care needs.

13.3 QUALITY OF LIFE

The measurement of quality of life in children is complicated by the rapid changes seen as children grow [17, 18] including the development of children's levels of literacy and understanding. For children under six years of age the use of simple child-completed scales or questionnaires completed by parents as proxies is the usual solution [19]. As children from three years of age will be recruited to this trial, one of the main measures of quality of life will be the Michigan Oral Health Related Quality of Life scale – Child Version (MOHRQOL-C)) [20] which is validated for use with children as young as 36 months.

Parents' assessment of the child's quality of life will be measured by asking them to complete the Michigan Oral Health Related Quality of Life – Parent Version (MOHRQOL-P).

In addition the children will be asked to evaluate their overall oral health-related quality of life by responding to two simple global ratings questions which are worded:

- "Would you say that the health of your teeth, lips, jaws and mouth is …?" with a 5-point response format ranging from 'Excellent' to 'Poor'
- "How much does the condition of your teeth, lips, jaws or mouth affect your life overall?" with a response range from 'Not at all' to 'Very much'

These questions are taken from the Child Perceptions Questionnaire (CPQ_{11-14}). The CPQ is a 41 item questionnaire developed by a recognised method to include items relevant to children with dental conditions. It was found to have acceptable internal consistency, reproducibility, criterion and construct validity when used in a dental clinic/practice population in the UK. These questions have been widely used with children as global ratings of quality of life [22], including in several UK studies [23] and their acceptability for use in young children will be assessed by the panels of children and parents as part of the feasibility study of this trial.

Parents' assessment of their child's overall oral health-related quality of life will be measured by asking them to respond to 2 global ratings questions from the Parental Caregivers Perceptions Questionnaire (PCP-Q_{6-14}) which is the parent version of the CPQ_{11-14}.

These measures of oral health related quality of life will be taken at baseline and at the end of the study.

13.4 DENTAL ANXIETY

In addition to quality of life, the dental anxiety of children will also be assessed. The Modified Child Dental Anxiety Scale (MCDAS) is a rating scale based on faces instead of the original numeric form. The reliability and validity of MCDAS has previously been evaluated for use in children in the UK [24] and its acceptability for use in young children will be assessed by the panels of children and parents as part of the feasibility study of this trial. The MCDAS will be administered at baseline and every recall and treatment appointment as this will be used to give information on their perceptions of each treatment experience.

At the start of each appointment the child will be given a faces VAS to report on their level of anxiety prior to arriving at the dentist's for their appointment. They will also be given a faces VAS following treatment to report on their level of anxiety during treatment.

Parents' assessment of their child's anxiety level prior to arriving at the dentist's for their appointment will also be recorded using a VAS. They will also be given a VAS following treatment to report on their assessment of their child's anxiety level during treatment.

13.5 ECONOMIC DATA

The main focus for the pilot rehearsal trial will be to develop and test out the methods and data capture tools planned for the main FiCTION Study. For each enrolled patient we will record the number of dental visits and details of any treatments undertaken.

At the end of this trial, if a recommendation is made about one management strategy being more effective than another, an appropriate fee structure and an understanding of the opportunity costs of this management strategy will be essential prior to recommendation for its implementation within the

NHS. The current fee structures in England and Scotland are largely historic and it is known that they influence practice. However, they do not necessarily represent the costs related to the dentists' time and materials and may result in perverse incentives. Furthermore there is no specific fee for some of the treatments. Consequently, a "procedure cost" using time in the surgery and material used will be applied for the common operative interventions in the surgical, biological and prevention alone arms. These will be based on data recorded on the CRF.

Parental costs (such as time off work) will be collected using questionnaires whilst the costs of onward referral (for example for hospital admission for extraction of painful teeth under general anaesthesia) can be obtained from existing data available within the NHS.

13.6 END OF STUDY

End of the pilot rehearsal trial is defined as last patient last visit. Consent will be sought from participants in the pilot rehearsal trial to follow them up as part of the main FiCTION trial should it go ahead.

14 STATISTICS AND DATA ANALYSIS

The data analysis of pilot rehearsal trial data will be largely descriptive; its purpose is not to draw any conclusions about the effectiveness of the three treatment strategies.

The target sample size to be approached for the pilot rehearsal trial is 252 children who meet our eligibility criteria and are asked to participate. A key outcome will be the proportion of these children who agree to be randomised to the three treatment strategies. By approaching 252 children we will be able to estimate the recruitment rate with a standard error no larger than 3.2%. Assuming that 200 of these children are actually recruited we will be able to estimate the 6 monthly attrition rate with a standard error no larger than 3.5%. Children will be assessed for eligibility according to the inclusion/exclusion criteria in section 11 and those eligible will be recruited and randomised to one of three treatment strategies as described in section 7.2. We will observe the numbers of children who were randomised and retained in order to determine an interval estimate of the proportions recruited and who complete the 6 months follow up. Since the retention rate at 6 months may not fully inform the trial about longer term loss to follow-up, these children will subsequently be re-consented subject to ethics approval to be part of an extension study. They will then be followed up for the remainder of the project (i.e. through the main trial, although data from these children will not be included as participants in the main trial) if funded, to monitor for likely loss to follow up over time. In this way the trial team can anticipate potential causes for drop-out from the main study and where possible prevent this. Recruitment and retention rates will be monitored by the Trial Manager in the Trials Office and reported to the Trial Steering Committee. If the upper 95% confidence limit for the observed retention rate at 6 months is less than 90% we will regard this as evidence that the rate is unsatisfactory with negative implications for the external validity of the full trial. If we recruit 200 children to the trial the observed retention rate must be at least 85% to meet this condition.

The statistical analysis will be to generate interval estimates of all the key parameters of interest. As set out in previous sections these include the proportion of children who meet our eligibility criteria, the proportion of these children who are recruited, the proportion of these children who are successfully followed up at 6 months, the response rates to the quality of life measures and the observed rates of pain and sepsis at 6 months. The sample size requirements for the main trial will then be reviewed taking these estimates into account. No statistical inference will be undertaken as the sample size has not been powered to test particular hypotheses.

14.1 DATA COLLECTION AND RETENTION

To preserve confidentiality, all patients will be allocated a unique study identifier, which will be used on all data collection forms and questionnaires; names or addresses will not appear on completed questionnaires or case report forms. Only a limited number of members of the research team will be able to link this identifier to patient-identifiable details (name & address) which will be held on a password protected database. All study documentation will be held in secure offices, and the research team will operate to a signed code of confidentiality. Transmission of identifiable data between practices, coordinating centres, the NCTU and the University of Dundee (the study sponsor) will be by secure fax, registered post or carried by a study team member. A clinical data management software package (Symphony) will be used for data entry and processing, allowing a full audit trail of any alterations made to the data post entry. Original questionnaires, case report forms and consent forms will be securely archived at the University of Dundee for 7 years following publication of the last paper or report from the study.

15 REGULATORY ISSUES

15.1 ETHICS APPROVAL

The conduct of this study will be in accordance with the ethical principles set out in the Declaration of Helsinki (2008).

Ethical and R&D approval of the protocol will be sought prior to commencement of the study. Local approvals (site specific assessments) will be sought before recruitment commences at each site (general dental practice).

15.2 CONSENT

The parent(s)/legal guardian(s) of all children in the study will provide written informed consent before any study procedures are carried out and a participant information sheet will be provided to facilitate this process. In so far as possible, and with the agreement of the parent(s)/legal guardian(s), participating children will also be asked to provide written or oral assent. Those not competent in English will be invited to bring an interpreter with them to the recall appointment or to request an NHS interpreter where this service is available.

As part of the consent process parent(s)/legal guardian(s) must agree to researchers & regulatory representatives having access to their medical records for monitoring and audit purposes.

Parent(s)/legal guardian(s) will also be informed that they have the right to withdraw from the study at any time. The right to refuse to participate without giving reasons will be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so will be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants will be free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment. For longer term follow up participants will be re-consented subject to ethical approval to allow data to be collected for the duration of the main study, if this is funded.

15.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and the Sponsor organisation will ensure that the study is registered under the Data Protection Act.

15.4 INDEMNITY

Indemnity in respect of negligent conduct will be covered by the individual GDPs professional indemnity arrangements. Indemnity in respect of protocol authorship will be provided through a Dundee, Leeds and Newcastle Universities' public liability insurance. Indemnity in respect of study management will be provided by the University of Dundee, in its role as sponsor. There is no provision for indemnity in respect of non-negligent harm.

15.5 SPONSOR

University of Dundee will act as the main sponsor for this study. Delegated responsibilities will be assigned to the Newcastle Clinical Trials Unit.

15.6 FUNDING

The NIHR HTA is funding this study. As the setting for this trial is general dental practice and data collection is taking place within the "normal" appointments that these patients would be attending anyway there is no provision to reimburse participants for taking part in the study.

15.7 AUDITS

The study may be subject to inspection and audit, as part of their routine 10% or 'for cause' by the University of Dundee under their remit as sponsor and by other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

15.8 STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through the Newcastle Clinical Trials Unit.

16 PUBLICATION POLICY

The results of the study will be published as a report for the NIHR HTA, and may be published as research papers in academic journals. Each of the participating PIs will be eligible for authorship on the NIHR HTA report. The CI (Nicola Innes) will be first author on the NIHR HTA report. The study may be presented at scientific conferences and other similar events. No individual patient participating in the trial will be identified from any study report. Authorship on peer-reviewed publications arising from this pilot rehearsal trial will include the chief investigator, grant co-applicants and members of the clinical trials coordinating team (statistician & Trial Manager). The NIHR HTA will be acknowledged on each publication.

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18 APPENDICES

18.1 Investigations and assessments
18.2 Adverse events
18.3 Covering letter, PIS, Consent form/Assent forms
18.4 Questionnaires

18.1 APPENDIX 1: SUMMARY OF INVESTIGATIONS AND ASSESSMENTS

Assessment	Completed by:	Location for assessment	Consent and baseline examination appointment	Initial Treatment Appointment	Scheduled appointment	Emergency appointment	6 month follow-up
Bitewing Radiographs	GDP	Site	Risk-based in line with guidance. **NOT A STUDY INVESTIGATION.**				
Quality of life: child	Child	Site	X				X
Quality of Life: parent	Parent	Site	X				X
MCDAS & worry	Child	Site	X	X	X	X	X
Pain DDQ8	Parent	Site		X	X	X	X
Pain: pre/post treatment questions to child: VAS	Child	Site		X	X	X	X
Pain: pre/post treatment questions to parent	Parent	Site		X	X	X	X
Economic questions	Parent	Site			X	X	X
Treatment preferences	Parent	Site					X
ICDAS (CRF)	GDP	Site		X			
Adverse Event recording (CRF)	GDP	Site		X	X	X	X
Pain: post treatment questions to GDP (CRF)	GDP	Site		X	X	X	X
Cooperation (CRF)	GDP	Site		X	X	X	X
Intervention Cost data (CRF)	GDP	Site		X	X	X	X

18.2 APPENDIX 2: ADVERSE EVENTS

	Adverse event		
Procedure	**Common & well understood consequences of treatment**	**Less common & unpleasant side effects**	**Rare events**
Fillings in teeth and crowns on teeth (conventional)	• occlusal discomfort • damage to adjacent teeth • caries progression	• pain, pulpitis • localised reaction to bonding agents or filling materials • dental abscess • facial swelling	• trauma to soft tissues
Crowns on teeth (Hall)	• immediate gingival discomfort/ pain • occlusal discomfort	• longer lasting gingival pain • pulpitis • dental abscess • facial swelling	• localised reaction to crowns
Local Anaesthetic	• pain at site of injection (during or immediately following injection)	• self-inflicted trauma to soft tissues	• trismus • prolonged altered sensation • swelling • haematoma • allergic reaction
Extraction of tooth	• pain around site • swelling	• early and delayed post extraction bleeding • infection of socket	• TMJ pain
Fluoride varnish			• nausea post-application • allergic reaction
Fissure sealants		• caries progression	
Acid etch on teeth prior to restoration or fissure sealant		• discomfort and minor irritation of oral tissues	

18.3 APPENDIX 3: PIS, CONSENT & ASSENT FORMS

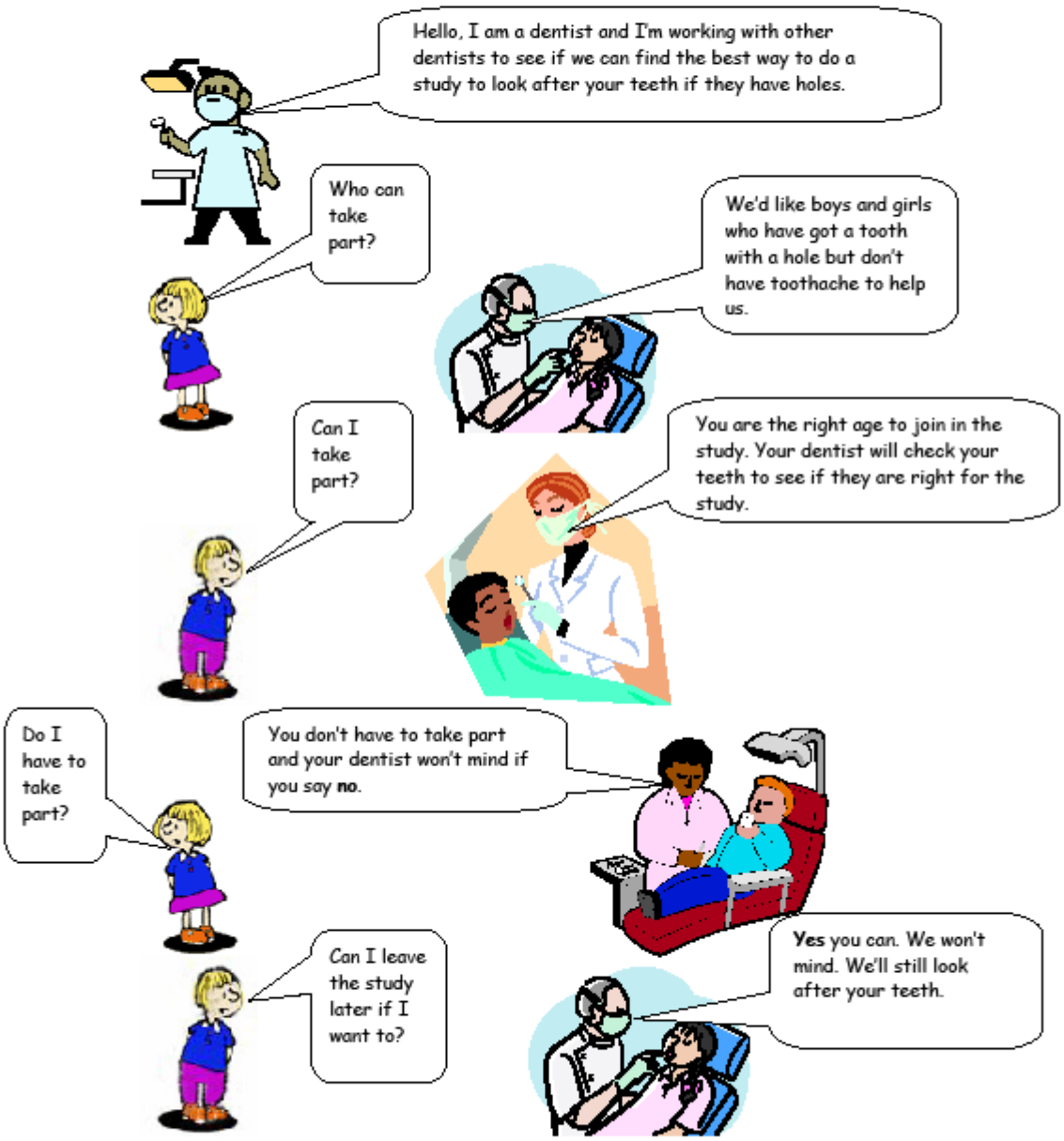
FiCTION Pilot
Child's information sheet (3-5 yrs)
ISRCTN77044005

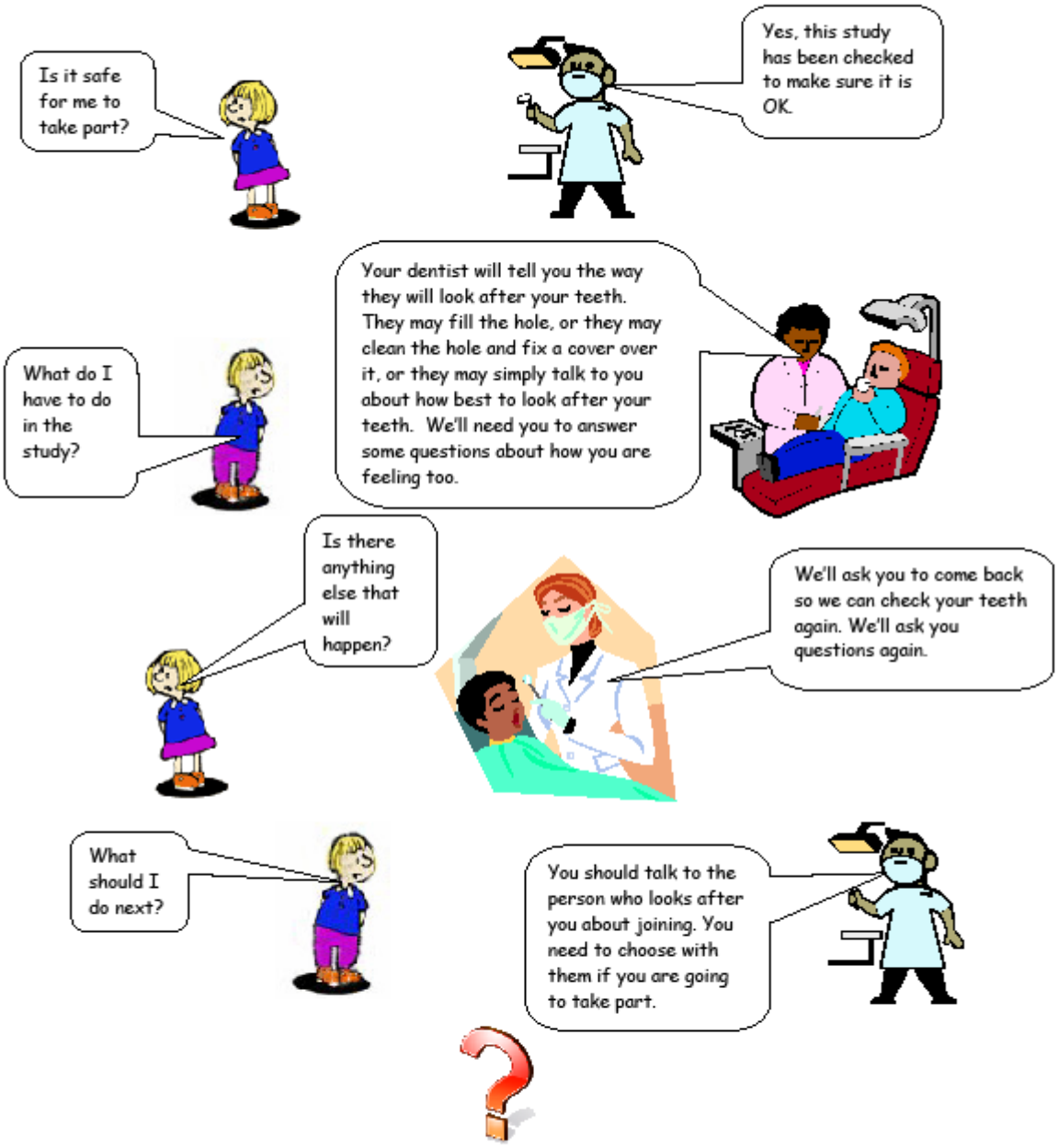
TRUST LETTERHEAD

Version 1.1
09/12/09

A pilot study about the best way to fix children's teeth

Patient information sheet for children





If you have any more questions about this study you can ask your dentist.

The person in charge of the study is Nicola and her telephone number is 01382 425 760.

A study about the best way to fill children's teeth

Patient identification number:

				1			

Assent form

	Please put a circle round the one you agree with:
1. Has someone read to you information about this study?	Yes / No
2. Has somebody else told you what this study is about?	Yes / No
3. Do you understand what this study is about?	Yes / No
4. Have you asked all the questions you want?	Yes / No
5. Have your questions been answered OK?	Yes / No
6. Do you understand it's OK to stop taking part at any time?	Yes / No
7. Are you happy to take part?	Yes / No

If any answers are 'no' or you don't want to take part, don't write your name!

If you do want to take part, you can write your name below.

Name of child (please PRINT name)	Date	Child to write name here
Name of person taking consent	Date	Signature

A pilot study about the best way to look after children's teeth

Parent information sheet

We invite you to participate in a research project. We believe it to be of potential importance. However, before you decide whether or not you wish to participate, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Read it carefully and be sure to ask any questions you have, and, if you want, discuss it with outsiders. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.

There is a separate information sheet for your child, written in child-friendly language, enclosed with this information leaflet. We suggest you decide together about taking part.

What is this Pilot Study about?

This study is about how to look after children's teeth which have decayed (gone bad). As you may know many dentists often drill and then fill milk (baby) teeth that have decay in them. However, this is not the only way they can look after decayed teeth. The main study plans to compare three different ways dentists can look after decayed teeth to find out which works best. However, before we can run the main study we need to make sure that it is possible and acceptable to parents, children and dentists. To do this, we run a pilot study in which we do the things we plan to do in the main study, but we work with a smaller number of people to check that everything is OK before we start the main study.

In this pilot study we will be using three different ways of looking after decayed teeth. Each of the three ways is used already by dentists. We want to find out which one of them is best for children.

What are these three ways?

The way your child's teeth will be looked after will be chosen at random from these three ways:-

1. **Surgical management of decay, with prevention**

   Surgical management is commonly known as the 'drill and fill' method of treating a decayed tooth. In this treatment the tooth is numbed with a dental injection, the decay is drilled out and a filling put in the tooth. To prevent decay your dentist will also explain the best way to brush and look after your child's teeth in the future

2. **Biological management of decay, with prevention**

   In this treatment rather than drilling out the decay and filling the hole, the decay is sealed off from the mouth by a filling or a metal crown to stop it getting worse. Sometimes some decay is removed before the tooth is sealed, but it is only from the surface of the tooth and no injections are needed. To prevent decay your dentist will explain the best way to brush and look after your child's teeth in the future.

3. **No fillings, prevention alone**

   It is possible to slow down the rate of tooth decay and to stop a decayed tooth from getting worse without having to use fillings. This involves things that you can do at home (which the dentist can give you advice about) as well as some simple things that the dentist can do when you come to the dental surgery.

Can I choose which of the three treatments my child gets?

It is not possible for you to choose which of the treatments your child will get because when we do not know which is the treatment that works best, we need to compare different approaches. For the comparison to be fair, we need to make sure that there is no difference between the people in the groups that are being compared. We do this by using a computer to put people into groups at **random** – like tossing a coin or throwing a dice - rather than by choice.

There are three ways of looking after decayed teeth in this study and everyone taking part has the same chance of getting any one of the three. All three treatments are used by dentists at the moment but no one has done a big study to compare which one works best.

Why have you asked my child to take part?

We are sending this information to the parents of all children who are 3-7 years old, who are due to have a check-up by the dentist. If that check-up shows that your child has decay in one of their milk teeth, (an x-ray might be used to help check this) but does not have any toothache or infection, your child will be suitable for this study. Your dentist will tell you whether your child is suitable and will ask if you would like your child to take part.

Do we have to take part?

No, it is up to you and your child to decide whether or not to take part. Your child will continue to get the best possible care no matter what you decide to do. Dentists are not being paid to include patients in the study.

If you and your child decide to take part you will be asked to sign a consent form. With your permission, your child will also be asked if they are willing to take part. If you change your minds later and you don't want to take part

anymore, no one will mind and your dentist will still look after your child's teeth in the best way they can. You will have **two** options if you wish to take your child out of the study.

1. Withdrawing partially
   Asking for a change in treatment but continuing to provide follow-up data by attending the dentist for visits as usual and completing follow-up questionnaires.
2. Withdrawing completely
   Taking no further part in the study (no further study visits or data collection).

   If you choose option 2 we would like to keep any data collected about you and your child up to the point you withdraw from the study.

What will happen if I agree my child will take part?

Before you agree to take part, you should ask your dentist any questions you might have. They will be pleased to answer any questions. You will be given a copy of your signed consent form and this information sheet to keep. If English is not your first language, you may want to take someone with you to act as an interpreter.

After consent is given, you will be asked to fill in a short questionnaire and a follow up appointment will be made. Before you bring your child back for this follow up appointment, the way your child's teeth will be looked after will be chosen at random from the three ways described above. Your dentist will then look after their teeth in this way for about 6 months. Each time your child sees the dentist there will be a short questionnaire for your child to complete. At the start of the study and after six months, we will also ask you to complete some questionnaires about your child. This is so we get a fuller picture of you and your child's experiences in the study than by only asking your child.

Are there any risks to taking part?

None of the treatments we are testing in this study are new. They are all safe and used already by many dentists. We want your child to be safe in the study at all times, but all treatments carry some minor risks even if they are very rare. You can discuss this with your dentist if you have any concerns. Although not a risk, we understand some children find some methods of treating tooth decay unpleasant. As with any dental treatment, if pain or discomfort persists beyond that expected, you should consult your dentist.

Are there any possible benefits of taking part?

We cannot promise the study will help your child directly but the information we get could help dentists look after children's teeth in the best way in the future. However, by taking part in this trial someone at the practice will spend time with you and your child making sure you both know how best to care for their teeth.

What if new information becomes available?

Sometimes during the course of a research project we may get new information. If this happens, we will tell you about it and discuss how it may affect your child's care.

What happens to the results of the pilot trial?

All study data are anonymous – this means that your personal details and those of your child do not appear.

The results of the pilot trial will go into a report we send back to the organisation funding this study; the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme (http://www.ncchta.org). Your child's name will not appear in any reports about the study.

The NIHR-HTA will then decide whether to go ahead with the main study. The results of the pilot study may be put online or printed in dental journals, which are read by dentists and their staff. The findings may also be presented at conferences where they can be shared with other dentists, healthcare professionals and researchers.

Will anyone else know my child is in this study?

We will keep your and your child's details and study information confidential. Only key people who have a need or a right, will know you are in the study.

The study is being overseen by the Newcastle Clinical Trials Unit (NCTU) which is part of Newcastle University. Authorised people from the NCTU and from the research team in Dundee University will look at anonymised data collected from the study whilst conducting the analysis. The trial manager and/or trial monitor and auditors from Dundee University may have access to personalised data like consent forms as they are responsible for the research.

Who is organising and funding the study?

This study has been funded by the NIHR Health Technology Assessment (HTA) programme (http://www.ncchta.org). It is being run by a team of researchers based in Dundee, Newcastle upon Tyne, Sheffield, Leeds, Cardiff and London and in a number of different dental practices across the country.

What if something goes wrong?

None of the treatments in this study are new and the risks of your child being harmed are very low. In the unlikely event that something does go wrong and your child is harmed during the research study there are no special compensation arrangements. If they are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Dundee University. The normal National Health Service complaints mechanisms will still be available to you.

Who has reviewed this study?

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Dundee University, NHS Tayside and the Regulatory Authorities, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Is there anything else I need to know about the pilot trial?

We are also conducting a series of focus groups with dentists and children and their parents. A focus group is a focused discussion where a researcher leads a group of participants through a set of questions on a particular topic. Information from these focus groups will help decide whether the main trial should be run and whether we need to make any changes to it before we start.

Some of the children asked to take part in the pilot trial might also be asked to take part in focus groups (with their parents) and vice versa. Participation in all the parts of the study is voluntary; if you are approached you do not need to take part if you don't want to.

If asked to take part in both the pilot trial and the focus groups, you and your child could decide to take part in both, one or neither.

As the focus groups are a separate part of the study, you would get another information sheet telling you about what is involved, and we would ask you to sign a separate consent form.

What if I have any more questions?

If you have any questions you can ask your dentist when you see them or you can contact any of the team below.

Meet the research team.

Name	Number
Senior Clinical Researcher	To be confirmed
Chris Speed, Newcastle Clinical Trials Unit	0191 222 6054
Dawn Greene, Newcastle Clinical Trials Unit	0191 222 7258
Dr Nicola Innes, University of Dundee	01382 425 760

A study about the best way to fill children's teeth

Patient identification number:

				2			

Consent form

	Please put your initials in the boxes if you agree:
1. I have read and understand the FiCTION Pilot Study information sheet version 1.1 dated 09/12/09 and have had the opportunity to ask questions.	
2. I understand that my child does not have to take part in the FiCTION Pilot Rehearsal Trial. I also understand that my child can opt out at any time, without giving a reason, and without this affecting his or her dental care or legal rights.	
3. I understand that sections of my child's dental records may be looked at by responsible individuals from Newcastle University or Dundee University. I give permission for these individuals to have access to my child's records.	
4. I understand that the anonymous data collected during the study, may be looked at by responsible individuals from the study team and from regulatory authorities or from the NHS Trust (England) or NHS Tayside, where it is relevant to my child taking part in this research. I give permission for these individuals to have these data.	
5. I agree to my child being included in the FiCTION Pilot Study.	
6. I agree to the information provided in this study being managed by the Newcastle Clinical Trials Unit.	

Name of parent **(Please PRINT name and give title eg Mr/Mrs/Ms/Miss)**	Date	Signature
Name of person taking consent	Date	Signature

Filling Children's Teeth: Indicated or Not? (FiCTION)

Rehearsal Pilot Trial

Dentists' and Dental Nurses' Information Sheet

What is the FiCTION study?

FiCTION is a multicentre trial funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA), comparing 3 different methods of treating caries in the primary dentition (See http://www.ncchta.org/project/1783.asp).

We are asking you to give consent to take part in the Rehearsal Pilot Trial for this study. Before you decide about taking part, we are providing you with the information you will need to understand why the research is being done and what it will involve for you and the practice. Please could you read this following information thoroughly and feel free to discuss it with colleagues if you wish.

What is the FiCTION Rehearsal Pilot Trial?

As you will be aware, traditional methods for restoring carious primary teeth (local anaesthesia, complete removal of caries and restoration) have recently been challenged and there is uncertainty as to the relative effectiveness of different approaches. The FiCTION Trial will compare three different treatment approaches for managing decayed teeth in children aged 3 to 11 to find out which is the most effective in general dental practice. Although there is some evidence supporting each approach, no conclusive evidence supports any one of them to the exclusion of the others in general dental practice today. This question of effective treatment for the primary dentition is fundamental

to delivering dentistry for children in the primary care setting. The FiCTION Main Trial will provide some definitive answers including which approach will reduce pain and sepsis and which is preferred. More details on the three treatments being compared can be found on our Website at www.fictiontrial.info.

Before we run the FiCTION Main Trial we need to carry out a Rehearsal Pilot Trial to ensure that the methods we propose are practicable and to inform any necessary changes. To carry out the Rehearsal Pilot Trial, we would like to work with a small sample of practices. We would be grateful if you could read this information sheet carefully and consider taking part in the FiCTION Rehearsal Pilot Trial.

Why have you asked me to take part?

We are seeking to recruit Primary Care General Dental Practices providing NHS dental services for children; three in Dundee, three in Newcastle and three in Sheffield. Your practice fits the criteria for eligibility for the FiCTION Main Trial. Participation is entirely voluntary.

What are the three treatments the FiCTION Rehearsal Pilot Trial will use?

As in the FiCTION Main Trial, children will be selected at random to receive one of three management options, each of which is based around a particular treatment philosophy:

Arm 1: Surgical management of decay, with best practice prevention

This arm is based on traditional management of decay, where local anaesthesia is placed, caries is completely removed and a restorative material or preformed metal (stainless steel) crown placed.

Arm 2: Biological management of decay, with best practice prevention

This arm is based around the concept of slowing or stopping caries through altering the environment to make it unfavourable for the disease process to progress, without necessarily using local anaesthetic or removing all of the caries. One way of doing this is through sealing caries into the teeth rather than completely removing it. This can be done using stainless steel/preformed metal crowns (The Hall Technique) or fissure sealants or with partial caries removal techniques.

Arm 3: Best practice prevention alone

In this arm, best practice prevention comprising toothbrushing advice, dietary investigation and advice, high fluoride varnish and fissure sealants, are used as the basis for a best practice preventive program which aims to slow or stop decay. The same prevention approach is followed for children in arms 2 and 3 also.

Full training in the protocol for each arm will be given to you and your dental nurse(s) before participant recruitment begins.

What will happen if I agree take part?

After we have consent from you that you are happy to take part, we will then arrange a convenient time to come to the practice to talk with and train staff in various aspects of the FiCTION study.

We will provide training in how participants are to be identified, contacted, recruited and randomised, along with training on the data capture software we use. We will also provide a training day for you and your dental nurse, on the techniques used in the interventions and the current best practice for prevention.

Study-involved staff in the practice will be appropriately trained in those aspects relevant to participating in this clinical trial. This will include being trained in the study protocol and in particular, the informed consent process.

What happens to the results of the Rehearsal Pilot Trial?

The results of the Rehearsal Pilot Trial will go into a report to the NIHR HTA which has funded this study. A decision will then be made as to whether the FiCTION Main Study should be run and if so what changes, if any, are needed to its design and conduct.

The results of the Rehearsal Pilot Trial may be disseminated in a variety of ways such as journals, presentations, and the FiCTION and HTA websites. All study data are anonymous.

Will taking part generate extra work for the practice?

There are a number of research specific duties that we have to ask you to perform (patient identification, taking informed consent, and administering the questionnaires); however, as an NIHR Portfolio Study financial support is available for these activities through your research network. Each dentist will be asked to recruit 15 eligible children from their patient list and follow them up for between 6 and 9 months.

Are there any risks to my patients taking part?

We want participants to be safe in the study at all times, but as you know, any treatment carries some minor risks even if they are very rare. All of the treatments we are testing in the FiCTION study are in current use.

Are there any possible benefits of taking part?

We cannot promise that taking part will benefit your patients directly; however the information we get will help define 'best practice' for the management of dental caries in children's teeth in the future. As part of this trial practice staff will have access to a variety of training opportunities which may be of benefit to them as well as the practice.

Who is organising and funding the study?

This study has been funded by the NIHR HTA. It is being run by a team of researchers based in Dundee, Glasgow, Newcastle upon Tyne, Sheffield, Leeds, Cardiff and London and in a number of different dentists' practices across the country.

What if something goes wrong?

In the event that something does go wrong and a participant is harmed during the Pilot Rehearsal Trial there are no special compensation arrangements. If they are harmed and this is due to someone's negligence then they may have grounds for a legal action for compensation against University of Dundee. The normal National Health Service complaints mechanisms will still be available to them.

Who has given ethical approval for this study?

FiCTION has been given a favourable opinion by the _____ Research Ethics Committee.

Is there anything else I need to know?

During the time that the Rehearsal Pilot Trial is running, we will also be conducting focus groups with dentists who have participated in the Rehearsal Pilot Trial. Information from these sessions will provide an opportunity for practices to feedback their experiences of the trial. As the focus groups are a separate element of the trial, participants will receive another information sheet telling them about what is involved and be asked to sign a separate consent form. Again, participation in the focus groups is entirely voluntary.

What if I have any more questions?

If you have further questions you can contact any of the team below.

Useful contacts:

Name	Number
Clinical leads	
Dundee: Dr Nicola Innes, University of Dundee	01382 425 760
Sheffield: Professor Chris Deery, University of Sheffield	0114 271 7885
Newcastle: Dr Anne Maguire, Newcastle University	0191 222 8564
Newcastle Clinical Trials Unit	
Chris Speed	0191 222 6054
Dawn Greene	0191 222 7258
Senior Clinical Researcher, University of Dundee	

18.4 APPENDIX 4: QUESTIONNAIRES

db	cc	pv	va

Area	Site	Participant	Time
		1	1

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

BASELINE

Questions about you and your teeth

Newcastle Clinical Trials Unit
Institute of Health and Society
21 Claremont Place,
Newcastle upon Tyne
NE2 4AA

☎ 0191 222 6054 / 7258

ISRCTN77044005

About these questions

In this booklet, you will find some questions about your teeth. Some are about your teeth in general and some about your teeth in particular. We also have some questions about your lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is an example of how to answer if you are a boy.

Are you

A boy..... (1)

A girl.....2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 2001

What is your date of birth?

1	9		0	4		0	1
day			month			year	

Please answer **every question**, unless the instructions tell you to do something else. Some of the questions may seem to be asking much the same thing, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

Remember that your name does not appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what you said.

These questions need to be read out and completed with the help of a member of staff from the practice.

Thanks for agreeing to help us with our study! This study is being done so we will understand more about the best way to care for your teeth. **PLEASE REMEMBER:**

- This is **not a test** and there are no right or wrong answers
- Just tell us what you think

Some questions about you

1. Are you:

(please circle the number that describes you)

A boy 1
A girl 2

---

2. How old are you?

(Please write how many years old you are in the box provided. For example if you are five years old please write 5 in the box provided)

☐ Years

Please now go to the next page.

Now we'd like to ask you some questions about your teeth

3.

a. Do your teeth hurt you now? **(please circle one number only)**

Yes 1
No 2

---

b. Do your teeth hurt when you eat something hot or cold? **(please circle one number only)**

Yes 1

No 2

---

c. Do your teeth hurt when you eat something sweet? **(please circle one number only)**

Yes 1

No 2

---

d. Do your teeth hurt when you chew or bite? **(please circle one number only)**

Yes 1

No 2

---

e. Does it hurt when you open your mouth wide? **(please circle one number only)**

Yes 1

No 2

---

f. Do you hear a noise (clicking) here (POINT TO TMJ AREA) when you open your mouth wide and close it? **(please circle one number only)**

Yes 1

No 2

Please now go to the next page.

g. Do the sides of your face hurt when you chew on tough food? **(please circle one number only)**

Yes.....1

No 2

---

h. Does a hurting tooth ever wake you up at night? **(please circle one number only)**

Yes.....1

No 2

---

i. Does a hurting tooth ever stop you from playing? **(please circle one number only)**

Yes.....1

No 2

---

j. Does a tooth ever hurt you while you are in school? **(please circle one number only)**

Yes.....1

No 2

Not at school.....3

---

k. Does a hurting tooth ever keep you home from school? **(please circle one number only)**

Yes.....1

No 2

Not at school.....3

---

l. Does a hurting tooth keep you from learning in school? **(please circle one number only)**

Yes.....1

No 2

Not at school.....3

Please now go to the next page.

m. Does a hurting tooth ever keep you from paying attention in school? **(please circle one number only)**

Yes.....1

No 2

Not at school.....3

---

n. Do you like your teeth? **(please circle one number only)**

Yes.....1

No 2

---

o. Do you have a nice smile? **(please circle one number only)**

Yes.....1

No 2

---

p. Do kids make fun of your teeth? **(please circle one number only)**

Yes.....1

No 2

---

q. Do you want braces for your teeth? **(please circle one number only)**

Yes.....1

No 2

---

r. Are you happy with your teeth? **(please circle one number only)**

Yes.....1

No 2

Please now go to the next page.

s. If no, please, tell me why you are not happy?

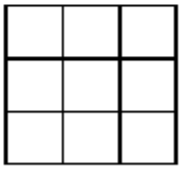
(Briefly note what was said)

.....

.....

.....

.....



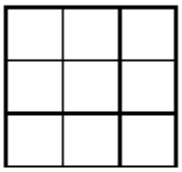
t. Is there anything else you want to tell us about your teeth?

.....

.....

.....

.....



Please now go to the next page

4. For these next questions I would like you to tell me how relaxed or worried you get about going to the dentist and what happens at the dentist.

To show me how relaxed or worried you feel, please use the simple scale below. The scale is a just like a ruler going from 1, which would show that you are relaxed, to 5 which would show that you are very worried.

1 would mean : relaxed/ not worried
2 would mean : very slightly worried
3 would mean : fairly worried
4 would mean : worried a lot
5 would mean : very worried

How do you feel about:					
a) going to the dentist generally	1	2	3	4	5
b) having your teeth looked at?	1	2	3	4	5
c) having your teeth scraped and polished?	1	2	3	4	5
d) having an injection in your gum?	1	2	3	4	5
e) having a filling?	1	2	3	4	5
f) having a tooth taken out?	1	2	3	4	5

Please now go to the next page.

Please answer these next 2 questions about your teeth in general.

5. Would you say the health of your teeth, lips, jaws and mouth is: (please circle the number *that best matches your answer)*

Excellent 1

Very good 2

Good 3

Fair 4

Poor 5

6. How much does the condition of your teeth, lips, jaws or mouth affect your life overall? (please circle the number that best matches your answer)

Not at all 1

Very little 2

Some 3

A lot 4

Very much 5

7. Before you saw the dentist today, were you?

(Please ask child to circle the face that describes how **worried** they were)

1 2 3 4 5

Please now give the questionnaire to a member of staff at the Dental practice. You will fill in the remaining questions at your next visit.

These questions must be filled in after you have had your treatment at the dentist.

We'd like you to tell us about how it felt at the dentist's today.

8. Thinking about your visit to the dentist today, were you?
(Please ask child to circle the face that describes how **worried** they were)

Not worried | | | | Very worried

1 2 3 4 5

9. Thinking about being at the dentist today, did it?
(*Please ask child to circle the face that describes the visit)*

Not hurt at all | | | | Hurt a lot

1 2 3 4 5

10. When did you answer these questions?

(Please write the date in the boxes below)

You've done it! Well done on answering all our questions!

Please now give the questionnaire to a member of staff at the Dental practice

db	cc	pv	va

Area		Site		Participant				Time
				2				1

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

BASELINE

About your child's teeth

Newcastle Clinical Trials Unit
Institute of Health and Society
21 Claremont Place,
Newcastle upon Tyne
NE2 4AA

☎ 0191 222 6054 / 7258

ISRCTN77044005

About these questions

In this booklet, you will find some questions about your child's teeth. Some are about your child's teeth in general and some about your child's teeth in particular. We also have some questions about your child's lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is an example of how to answer if you are a man.

Are you

A man..... (1)

A woman..... 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

1	9		0	4		8	0
day			month			year	

Please answer **every question**, unless the instructions tell you to do something else. Some of the questions may seem to be asking much the same thing, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

Remember that your name does not appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what you said.

Please now go to the next page

Thank-you for helping us with our study. We are asking for your help so we may understand more about the best way to look after children's teeth.

The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

First two questions about your child:

1. Is your child: (please circle the number that describes your child)

A boy 1
A girl 2

2. What is your child's date of birth?

(please write the date in the boxes below in the format dd-mm-yy)

☐☐ ☐☐ ☐☐

---

3. To which of the following ethnic groups does your child belong?

(Please circle the number that best describes your child)

White 1
Black 2
Indian, Pakistani or Bangladeshi 3
Chinese 4
Mixed race 5
Other *(please specify)* 6

Please now go to the next page

The next set of questions are about your child's teeth

4. **Please, tell me for each of the following statements how much you agree with it. Please circle your answer on the 5 point answer scale ranging from 1 = "disagree strongly" and 5 = "agree strongly".**

Statement	Disagree strongly				Agree strongly
a) My child has a toothache or pain currently.	1	2	3	4	5
b) My child's teeth hurt when he/she eats/ drinks something hot or cold.	1	2	3	4	5
c) My child's teeth hurt when he/she eats/ drinks something sweet.	1	2	3	4	5
d) My child's teeth hurt when he/she bites/ chews.	1	2	3	4	5
e) My child' has pain when he/she opens his/her mouth wide.	1	2	3	4	5
f) My child sometimes wakes up at night with a tooth ache.	1	2	3	4	5
g) My child sometimes has a tooth ache at school.	1	2	3	4	5
h) My child sometimes misses a day of school because of a toothache.	1	2	3	4	5
i) My child has a nice smile.	1	2	3	4	5
j) My child is happy with his / her teeth.	1	2	3	4	5
k) My child sometimes complains about his / her teeth.	1	2	3	4	5

Please now go to the next page

5. **How would you rate the health of your child's teeth, lips, jaws and mouth?**

Excellent 5

Very good.....4

Good 3

Fair.....2

Poor 1

---

6. **How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?**

Not at all.....1

Very little 2

Some.....3

A lot.....4

Very much.....5

Please hand this booklet back to a member of staff.

You will need to fill in the rest of the questions at the next treatment visit.

The following question should be filled out before your child has had their treatment.

7. **Before seeing the dentist today, do you think your child was?**

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

These next questions are about your child's behavior.

8. **Is your child:**

		Never	Sometimes	Often
a.	Biting things off with their back teeth instead of their front teeth?	1	2	3
b.	Putting sweets away just after starting eating?	1	2	3
c.	Starting to cry during meals?	1	2	3
d.	Having problems with brushing upper teeth?	1	2	3
e.	Having problems with brushing lower teeth?	1	2	3
f.	Having problems chewing?	1	2	3
g.	Chewing at one side?	1	2	3
h.	Suddenly reaching for his/her cheek while eating?	1	2	3

Please hand this booklet back to a member of staff.

You will need to fill in the rest of the questions after your child has had their treatment.

The following questions should be filled out **after** your child has had their treatment.

9. Thinking about being at the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

---

10. Thinking about being at the dentist today how do you think your child found the treatment?

Not at all painful 1

A little painful.....2

Somewhat painful.....3

Painful.....4

Very painful 5

---

11. Who completed this questionnaire? (*please circle the number that describes you*)

Mother.....1

Father.....2

Other (please state who)

.....3

Please now go to the next page

12. Were you present at the time of the visit?
(please circle the number that describes you)

Yes..... 1
No 2

---

13. Where were you during the visit?
(please circle the number that describes you)

In the surgery with my child 1
In the waiting room 2

---

14. When did you fill in this questionnaire?
(please write the date in the boxes below in the format dd-mm-yy)

☐☐ ☐☐ ☐☐

Please make sure you have answered **ALL** questions.

Please hand this booklet back to a member of staff.

THANK YOU
FOR YOUR HELP

db	cc	pv	va

Area		Site		Participant				Time
				1				2

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

SCHEDULED APPOINTMENT

Questions about you and your teeth

Newcastle Clinical Trials Unit
Institute of Health and Society
21 Claremont Place,
Newcastle upon Tyne
NE2 4AA

☎ 0191 222 6054 / 7258

ISRCTN77044005

About these questions

In this booklet, you will find some questions about your teeth. Some are about your teeth in general and some about your teeth in particular. We also have some questions about your lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are a boy.

Are you

A boy..... (1)

A girl 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 2001

What is your date of birth?

1	9		0	4		0	1
day			month			year	

Please answer **every question**, unless the instructions tell you to do something else. Some of the questions may seem to be asking much the same thing, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

Remember that your name does not appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what you said.

These questions need to be read out and completed with the help of a member of staff from the practice.

Thanks for agreeing to help us with our study! This study is being done so we will understand more about the best way to care for your teeth. **PLEASE REMEMBER:**

- This is **not a test** and there are no right or wrong answers
- Just tell us what you think

4. For these next questions I would like you to tell me how relaxed or worried you get about going to the dentist and what happens at the dentist.

To show me how relaxed or worried you feel, please use the simple scale below. The scale is a just like a ruler going from 1, which would show that you are relaxed, to 5 which would show that you are very worried.

1 would mean : relaxed/ not worried
2 would mean : very slightly worried
3 would mean : fairly worried
4 would mean : worried a lot
5 would mean : very worried

How do you feel about:					
a) going to the dentist generally	1	2	3	4	5
b) having your teeth looked at?	1	2	3	4	5
c) having your teeth scraped and polished?	1	2	3	4	5
d) having an injection in your gum?	1	2	3	4	5
e) having a filling?	1	2	3	4	5
f) having a tooth taken out?	1	2	3	4	5

Please now go to the next page.

2

5. Before you saw the dentist today, were you?

(Please ask child to circle the face that describes how **worried** they were)

Not worried — Very worried

1 2 3 4 5

Please now give the questionnaire to a member of staff at the Dental practice. You will fill in the remaining questions after your treatment.

This question must be filled in after you have had your treatment at the dentist.

We'd like you to tell us about how it felt at the dentist's today.

6. Thinking about your visit to the dentist today, were you?
(Please ask child to circle the face that describes how **worried** they were)

1 2 3 4 5

---

7. Thinking about being at the dentist today, did it?
(*Please ask child to circle the face that describes the visit)*

1 2 3 4 5

---

8. When did you answer these questions?

(Please write the date in the boxes below)

☐☐ ☐☐ ☐☐

You've done it! Well done on answering all our questions!

Please now give the questionnaire to a member of staff at the dental practice.

db	cc	pv	va

Area	Site	Participant	Time
		2	2

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

SCHEDULED APPOINTMENT

About your child's teeth

Newcastle Clinical Trials Unit
Institute of Health and Society
21 Claremont Place,
Newcastle upon Tyne
NE2 4AA

☎ 0191 222 6054 / 7258

ISRCTN77044005

About these questions

In this booklet, you will find some questions about your child's teeth. Some are about your child's teeth in general and some about your child's teeth in particular. We also have some questions about your child's lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is an example of how to answer if you are a man.

Are you

A man..... (1)

A woman..... 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

1	9		0	4		8	0
day			month			year	

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Please now go to the next page

Thank-you for helping us with our study. We are asking for your help so we may understand more about the best way to look after children's teeth.

The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

The following question should be filled out before your child has had their treatment.

1. **Before seeing the dentist today, do you think your child was?**

   Not at all worried 1

   Very slightly worried 2

   Fairly worried 3

   Quite worried.....4

   Very worried 5

Please now go to the next page

These next questions are about your child's behavior.

2. Is your child:

		Never	Sometimes	Often
a.	Biting things off with their back teeth instead of their front teeth?	1	2	3
b.	Putting sweets away just after starting eating?	1	2	3
c.	Starting to cry during meals?	1	2	3
d.	Having problems with brushing upper teeth?	1	2	3
e.	Having problems with brushing lower teeth?	1	2	3
f.	Having problems chewing?	1	2	3
g.	Chewing at one side?	1	2	3
h.	Suddenly reaching for his/her cheek while eating?	1	2	3

Please now go to the next page

These next questions refer to episodes of pain arising from tooth decay since your child's previous visit to this dentist.

3. **Was your child absent from school because of the pain arising from tooth decay? (Please circle response)**

Yes	1	Answer Q4
No	2	Go to Q5

4. **How long was your child absent from school because of the pain? (Please circle response)**

Less than one day	1
One day	2
Two days	3
Three days	4
Four days	5
More than five days	6

5. **Were you, or anyone else, required to take any time off work to look after your child?**

Yes	1	Answer Q6
No	2	Go to Q7

Please now go to the next page

6. How much time was taken off work?

Less than one day 1

One day .....2 ¦ ¦

Two days 3

Three days 4

Four days 5

More than five days¦ 6

---

7. Were you required to arrange any additional child-care for your child as a result of the pain arising from tooth decay?

Yes .....1¦ **Answer Q8**

No .....2¦ **Go to Q9**

---

8. How much extra child-care did you have to arrange for your child?

Less than one day 1

One day .....2 ¦ ¦

Two days 3

Three days 4

Four days 5

More than five days¦ 6

Please now go to the next page

9. Did your child need any pain-killing medicine because of the pain arising from tooth decay?

Yes .....1 → Answer Q10

No .....2 → Go to Q11

---

10. For how long did your child need the pain-killing medicine?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

More than five days 6

---

11. If you were unable to participate in your usual activities outside of work because of your child's pain arising from tooth decay, how long was this for?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

More than five days 6

Please now go to the next page

12. If your child was unable to participate in their usual activities outside of school because of the pain arising from tooth decay, how long was this for?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

More than five days 6

Please hand this booklet back to a member of staff.

You will need to fill in the rest of the questions after your child has had their treatment.

The following questions must be filled out after your child has had their treatment.

13. Thinking about being at the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

---

14. Thinking about being at the dentist today how do you think your child found the treatment?

Not at all painful 1

A little painful.....2

Somewhat painful.....3

Painful.....4

Very painful 5

---

15. Who completed this questionnaire? (*please circle the number that describes you*)

Mother.....1

Father.....2

Other (please state who)

.....3

---

16. Were you present at the time of the visit?
(*please circle the number that describes you*)

Yes..... 1

No 2

Please now go to the next page

17. Where were you during the visit?
(please circle the number that describes you)

In the surgery with my child 1

In the waiting room 2

---

18. When did you fill in this questionnaire?
(please write the date in the boxes below in the format dd-mm-yy)

☐☐ ☐☐ ☐☐

Please make sure you have answered **ALL** questions.

THANK YOU
FOR YOUR HELP

db	cc	pv	va

Area		Site		Participant				Time
				1				3

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

EMERGENCY APPOINTMENT

Questions about you and your teeth

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NE2 4AA

☎ 0191 222 6054 / 7258

ISRCTN77044005

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Are you

A boy..... (1)

A girl 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 2001

What is your date of birth?

1	9		0	4		0	1
day			month			year	

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4. For these next questions I would like you to tell me how relaxed or worried you get about going to the dentist and what happens at the dentist.

To show me how relaxed or worried you feel, please use the simple scale below. The scale is a just like a ruler going from 1, which would show that you are relaxed, to 5 which would show that you are very worried.

1 would mean : relaxed/ not worried
2 would mean : very slightly worried
3 would mean : fairly worried
4 would mean : worried a lot
5 would mean : very worried

How do you feel about:					
a) going to the dentist generally	1	2	3	4	5
b) having your teeth looked at?	1	2	3	4	5
c) having your teeth scraped and polished?	1	2	3	4	5
d) having an injection in your gum?	1	2	3	4	5
e) having a filling?	1	2	3	4	5
f) having a tooth taken out?	1	2	3	4	5

Please now go to the next page.

2

5. Before you saw the dentist today, were you?

(Please ask child to circle the face that describes how **worried** they were)

1 2 3 4 5

Please now give the questionnaire to a member of staff at the Dental practice. You will fill in the remaining questions after your treatment.

This question must be filled in after you have had your treatment at the dentist.

We'd like you to tell us about how it felt at the dentist's today.

6. Thinking about your visit to the dentist today, were you?
(Please ask child to circle the face that describes how **worried** they were)

1 2 3 4 5

---

7. Thinking about being at the dentist today, did it?
(*Please ask child to circle the face that describes the visit)*

1 2 3 4 5

---

8. When did you answer these questions?

(Please write the date in the boxes below)

☐☐ ☐☐ ☐☐

You've done it! Well done on answering all our questions!

Please now give the questionnaire to a member of staff at the dental practice.

db	cc	pv	va

Area	Site	Participant	Time
		2	3

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

EMERGENCY APPOINTMENT

About your child's teeth

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Yes .....1¦ **Answer Q8**

No .....2¦ **Go to Q9**

---

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Yes .....1 → **Answer Q10**

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No 2

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17. Where were you during the visit?
(please circle the number that describes you)

In the surgery with my child 1

In the waiting room 2

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18. When did you fill in this questionnaire?
(please write the date in the boxes below in the format dd-mm-yy)

☐☐ ☐☐ ☐☐

Please make sure you have answered **ALL** questions.

THANK YOU
FOR YOUR HELP

db	cc	pv	va

Area		Site		Participant				Time
				1				4

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

6-MONTH FOLLOW-UP

Questions about you and your teeth

Newcastle Clinical Trials Unit
Institute of Health and Society
21 Claremont Place,
Newcastle upon Tyne
NE2 4AA

☎ 0191 222 6054 / 7258

ISRCTN77044005

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A girl 2

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1	9		0	4		0	1
day			month			year	

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Thanks for agreeing to help us with our study! This study is being done so we will understand more about the best way to care for your teeth. **PLEASE REMEMBER:**

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- Just tell us what you think

Now we'd like to ask you some questions about your teeth

1.

a. Do your teeth hurt you now? **(please circle one number only)**

Yes 1
No 2

---

b. Do your teeth hurt when you eat something hot or cold? **(please circle one number only)**

Yes 1

No 2

---

c. Do your teeth hurt when you eat something sweet? **(please circle one number only)**

Yes 1

No 2

---

d. Do your teeth hurt when you chew or bite? **(please circle one number only)**

Yes 1

No 2

---

e. Does it hurt when you open your mouth wide? **(please circle one number only)**

Yes 1

No 2

Please now go to the next page.

f. Do you hear a noise (clicking) here (POINT TO TMJ AREA) when you open your mouth wide and close it? **(please circle one number only)**

Yes 1

No 2

---

g. Do the sides of your face hurt when you chew on tough food? **(please circle one number only)**

Yes 1

No 2

---

h. Does a hurting tooth ever wake you up at night? **(please circle one number only)**

Yes 1

No 2

---

i. Does a hurting tooth ever stop you from playing? **(please circle one number only)**

Yes 1

No 2

---

j. Does a tooth ever hurt you while you are in school? **(please circle one number only)**

Yes 1

No 2

Not at school 3

---

k. Does a hurting tooth ever keep you home from school? **(please circle one number only)**

Yes 1

No 2

Not at school 3

Please now go to the next page.

l. Does a hurting tooth keep you from learning in school? **(please circle one number only)**

Yes.....1

No 2

Not at school.....3

---

m. Does a hurting tooth ever keep you from paying attention in school? **(please circle one number only)**

Yes.....1

No 2

Not at school.....3

---

n. Do you like your teeth? **(please circle one number only)**

Yes.....1

No 2

---

o. Do you have a nice smile? **(please circle one number only)**

Yes.....1

No 2

---

p. Do kids make fun of your teeth? **(please circle one number only)**

Yes.....1

No 2

---

q. Do you want braces for your teeth? **(please circle one number only)**

Yes.....1

No 2

Please now go to the next page.

r. Are you happy with your teeth? **(please circle one number only)**

Yes.....1

No 2

---

s. If no, please, tell me why you are not happy?

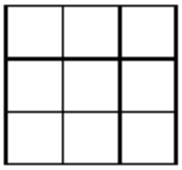
(Briefly note what was said)

.....

.....

.....

.....



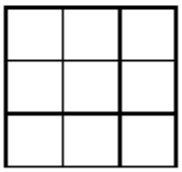
t. Is there anything else you want to tell us about your teeth?

.....

.....

.....

.....



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2. For these next questions I would like you to tell me how relaxed or worried you get about going to the dentist and what happens at the dentist.

To show me how relaxed or worried you feel, please use the simple scale below. The scale is a just like a ruler going from 1, which would show that you are relaxed, to 5 which would show that you are very worried.

1 would mean : relaxed/ not worried
2 would mean : very slightly worried
3 would mean : fairly worried
4 would mean : worried a lot
5 would mean : very worried

How do you feel about:					
a) going to the dentist generally	1	2	3	4	5
b) having your teeth looked at?	1	2	3	4	5
c) having your teeth scraped and polished?	1	2	3	4	5
d) having an injection in your gum?	1	2	3	4	5
e) having a filling?	1	2	3	4	5
f) having a tooth taken out?	1	2	3	4	5

Please now go to the next page.

Please answer these next 2 questions about your teeth in general.

3. Would you say the health of your teeth, lips, jaws and mouth is: (please circle the number *that best matches your answer)*

Excellent 1

Very good 2

Good 3

Fair 4

Poor 5

---

4. How much does the condition of your teeth, lips, jaws or mouth affect your life overall? (please circle the number that best matches your answer)

Not at all 1

Very little 2

Some 3

A lot 4

Very much 5

---

5. Before you saw the dentist today, were you?

(Please ask child to circle the face that describes how **worried** they were)

1 2 3 4 5

Please now give the questionnaire to a member of staff at the Dental practice. You will fill in the remaining questions after your treatment.

These questions must be filled in after you have had your treatment at the dentist.

We'd like you to tell us about how it felt at the dentist's today.

6. Thinking about your visit to the dentist today, were you?
   (Please ask child to circle the face that describes how **worried** they were)

Not worried — Very worried

1 2 3 4 5

---

7. Thinking about being at the dentist today, did it?
   (*Please ask child to circle the face that describes the visit)*

Not hurt at all — Hurt a lot

1 2 3 4 5

---

8. When did you answer these questions?

   (Please write the date in the boxes below)

You've done it! Well done on answering all our questions!

Please now give the questionnaire to a member of staff at the Dental practice

db	cc	pv	va

Area	Site	Participant	Time
		2	4

CONFIDENTIAL

FiCTION TRIAL

Managing Decay for Children

6-MONTH FOLLOW-UP

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Are you

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A woman..... 2

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What is your date of birth?

1	9		0	4		8	0
day			month			year	

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The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

The next set of questions are about your child's teeth

1. **Please, tell me for each of the following statements how much you agree with it. Please circle your answer on the 5 point answer scale ranging from 1 = "disagree strongly" and 5 = "agree strongly".**

Statement	Disagree strongly				Agree strongly
a) My child has a toothache or pain currently.	1	2	3	4	5
b) My child's teeth hurt when he/she eats/drinks something hot or cold.	1	2	3	4	5
c) My child's teeth hurt when he/she eats/drinks something sweet.	1	2	3	4	5
d) My child's teeth hurt when he/she bites/chews.	1	2	3	4	5
e) My child' has pain when he/she opens his/her mouth wide.	1	2	3	4	5
f) My child sometimes wakes up at night with a tooth ache.	1	2	3	4	5
g) My child sometimes has a tooth ache at school.	1	2	3	4	5
h) My child sometimes misses a day of school because of a toothache.	1	2	3	4	5
i) My child has a nice smile.	1	2	3	4	5
j) My child is happy with his / her teeth.	1	2	3	4	5
k) My child sometimes complains about his / her teeth.	1	2	3	4	5

Please now go to the next page

2. **How would you rate the health of your child's teeth, lips, jaws and mouth?**

Excellent 5

Very good.....4

Good 3

Fair.....2

Poor 1

---

3. **How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?**

Not at all.....1

Very little 2

Some.....3

A lot.....4

Very much 5

---

4. **Before seeing the dentist today, do you think your child was?**

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

Please now go to the next page.

These next questions are about your child's behavior.

5. Is your child:

		Never	Sometimes	Often
a.	biting things off with their back teeth instead of their front teeth?	1	2	3
b.	putting sweets away just after starting eating?	1	2	3
c.	starting to cry during meals?	1	2	3
d.	having problems with brushing upper teeth?	1	2	3
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f.	having problems chewing?	1	2	3
g.	chewing at one side?	1	2	3
h.	suddenly reaching for his/her cheek while eating?	1	2	3

Please now go to the next page.

These next questions refer to episodes of pain arising from tooth decay since your child's previous visit to this dentist.

6. **Was your child absent from school because of the pain arising from tooth decay? (Please circle response)**

Yes	1	Answer Q7
No	2	Go to Q8

---

7. **How long was your child absent from school because of the pain? (Please circle response)**

Less than one day	1
One day	2
Two days	3
Three days	4
Four days	5
More than five days	6

---

8. **Were you, or anyone else, required to take any time off work to look after your child?**

Yes	1	Answer Q9
No	2	Go to Q10

These next questions refer to episodes of pain arising from tooth decay since your child's previous visit to this dentist.

6. **Was your child absent from school because of the pain arising from tooth decay? (Please circle response)**

Yes	1	Answer Q7
No	2	Go to Q8

---

7. **How long was your child absent from school because of the pain? (Please circle response)**

Less than one day	1
One day	2
Two days	3
Three days	4
Four days	5
More than five days	6

---

8. **Were you, or anyone else, required to take any time off work to look after your child?**

Yes	1	Answer Q9
No	2	Go to Q10

---

12. Did your child need any pain-killing medicine because of the pain arising from tooth decay?

Yes .....1 → **Answer Q13**

No .....2 → **Go to Q14**

---

13. For how long did your child need the pain-killing medicine?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

More than five days 6

---

14. If you were unable to participate in your usual activities outside of work because of your child's pain arising from tooth decay, how long was this for?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

More than five days 6

---

15. If your child was unable to participate in their usual activities outside of school because of the pain arising from tooth decay, how long was this for?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

More than five days 6

Please hand this booklet back to a member of staff.

You will need to fill in the rest of the questions after your child has had their treatment.

The following questions must be filled out after your child has had their treatment.

16. Before seeing the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

---

17. Thinking about being at the dentist today how do you think your child found the treatment?

Not at all painful 1

A little painful.....2

Somewhat painful.....3

Painful.....4

Very painful.....5

---

18. Who completed this questionnaire? (*please circle the number that describes you*)

Mother.....1

Father.....2

Other (please state who)

.....3

---

19. Were you present at the time of the visit?
(*please circle the number that describes you*)
Yes..... 1

No 2

Please now go to the next page.

20. Where were you during the visit?

(please circle the number that describes you)

In the surgery with my child 1

In the waiting room 2

Please now go to the next page.

The next set of questions are about your treatment preferences.

21. Were you happy for your child's dental treatment to be chosen at random in the study for you? (*Please circle the number that best applies to you*)

Yes 1

No 2

---

22. Were you happy with the dental treatment method that your child got? (*Please circle the number that best applies to you*)

Yes 1

No 2

---

23. If you had been asked to choose a treatment method, which one would you have chosen? (*Please circle the number that best applies to you*)

Drill and fill (surgical) 1

Sealing in decay (biological) 2

No fillings (prevention alone) 3

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24. When did you fill in this questionnaire?

(please write the date in the boxes below in the format dd-mm-yy)

☐☐ ☐☐ ☐☐

Please make sure you have answered **ALL** questions.

THANK YOU
FOR YOUR HELP