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Dental RECUR Trial

Submission date 27/09/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/09/2013	**Overall study status** Completed	
Last Edited 18/03/2022	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
One in two children in Salford and Manchester aged 5 years has tooth decay. Many of those children have had a tooth extracted. Removal of teeth under general anaesthestic is the single most common reason for planned admission to hospital for children under 11. Children who have already had teeth extracted are at higher risk of further decay and extractions of permanent teeth in the future. Lack of attendance for regular dental care, despite obvious need, is recognised as neglect under national UK guidelines and, in some cases, indicates that a child is at general risk of neglect. In our research, we have found that parents of children who have teeth extracted for tooth decay, by local/general anaesthetic or sedation, are less likely to attend for regular dental care themselves and more likely to be afraid of dentists. They can experience uncertainty about whether to take their child for care and are less likely to feel they can undertake preventive dental care. A new service has been designed recognising that these families face tough challenges, and deprivation can result in poor child dental health. The new service will use a new approach using Motivational Interviewing techniques, to work with families. This type of service has been successfully researched in disadvantaged communities in the USA. The aim of this study is to find out whether this new dental service helps families to prevent their child from developing more tooth decay.

Who can participate?
Families who have children aged 5-7 who are having one or more teeth at a secondary care centre.

What does the study involve?
Families are randomly allocated to either the new service or to the usual follow-up care. All participants are given help to find and register with a local family dentist if they wish. Every child is given a free dental check up two years after the extraction. This is done at the child's school by a dentist trained in looking for dental decay in children. All families are invited to attend a review appointment at some point between in the first six weeks following tooth extraction. The session will be delivered by a dental nurse. For families in the new service group, the session will look at ways to help prevent further decay in the child's remaining first teeth and permanent teeth. The new service group families are also invited for an appointment with their dentist every three months for a year. At the end of the year the child will go back to visiting their

dentist as normal. For families in the usual follow up care group, the session will look at future dental development for their child. At the end of the session families in this group will go back to visiting their dentist as normal.

What are the possible benefits and risks of participating?
There is no direct benefit from being in the study and participants will not receive any payment. It will not affect access to any other dental or medical services. All families will be provided with a £5 voucher when they attend their review appointment towards any out of pocket expenses. We will collect information about the children's dental health from the check-ups in school and from any visits to their family dentist. Participants will also be asked to complete a dental health survey on three occasions throughout the study. Any results that are made public will not contain any information that can identify anyone personally. It is very unlikely that participants' health or wellbeing will be made worse by the services being evaluated in this study. Taking part in the study will not affect access to dental or other services.

Where is the study run from?
Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2014 to December 2018

Who is funding the study?
National Institute for Health Research, Research for Patient Benefit Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

15284

Study information

Scientific Title
Comparison of a new with standard child and family primary care service to reduce the re-occurrence of childhood dental caries (Dental RECUR Trial)

Study objectives
Current hypothesis as of 22/10/2015:
Will a new dental service partly delivered in a community setting led by dental nurses who have been trained in a brief negotiated intervention using motivational interviewing principles to develop tailored support to enhance parental efficacy in dental health-related behaviours, be a more cost-effective service than that currently offered in the UK by dentists in dental practices, in reducing the re-occurrence of dental decay within two years in young children with previous dental extractions?

Previous hypothesis:
Will a new dental service led by dental nurses who have been trained in motivational interviewing to develop tailored support to enhance parental efficacy in dental health-related behaviours, be a more cost-effective service than that currently offered in England by dentists in dental practices, in reducing the re-occurrence of dental decay within 2 years in young children with previous dental extractions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester Central, 19/07/2013, 13/NW/0466

Study design
Randomised interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

Interventions
Current interventions as of 08/07/2014:
Parents/guardians of children aged between 5 and 7 years who are booked for an extraction for tooth decay, will be invited to take part. All participants will be asked to attend a review appointment at some point between enrolment (the consent point) and the six weeks post-operative period2-6 weeks post extraction. If the appointment is to take place after the extraction date parents will have an appointment made for their review appointment before

leaving the secondary care centre on the day of their extraction appointment. Participants will be given an appointment card and will be sent a text reminder the day before the review. At the review appointment participants will be randomly allocated to either Group 1: DR-BNI (TEST) or Group 2: Dental Development (CONTROL).

Group 1 (test group): Brief Negotiated Interview (DR-BNI)
The review appointment will be conducted by an Additional Skills Dental Nurse (ASDNs) or dental therapists trained by the research team principles of motivational interviewing. The session will be tape recorded and start with a review of the dental extraction (if it has occurred), the discussion will then move onto future dental care and the Dental RECUR Brief Negotiated Interview (DR-BNI) will be delivered. The session will establish parents' stage of change and allow a tailored programme to be planned in relation to enhancing parental efficacy in three key child dental health-related behaviours: establishing twice daily toothbrushing with fluoridated toothpaste, particularly night time; reducing frequency of sugary foods and drinks; attending for preventive rather than symptomatic dental care. At the end of the appointment the ASDN will assist the participant to make the first of their quarterly recall appointments with their General Dental Practitioner (GDP). If the participant does not have a GDP the ASDN will assist the participant in finding a local practice and making their first appointment if appropriate. The review appointment will take approximately 1 hour.

The participant's GDP will have been informed of their patients' involvement in the research and advice regarding frequency of recall visits and preventive care (as advised by the Department of Health [DH] in Delivering Better Oral Health [a guidance manual on recommended prevention provided to each GDP by DH]). This guidance recommends that high caries risk child patients are recalled at 3, 6, 9 and 12 months post extraction. The first recall appointment will be arranged during the ASDN- led review (above), all subsequent quarterly recall appointments will be organised between the participant and their GDP. It is anticipated that the GDP will have a text message service to remind parents of their appointment prior to each recall. We will ask the participant's GDP to complete a CRF and send it back to the co-ordinating centre each time the participant attends their dental practice in the first year.

There will be no active intervention in the second year and the practice will be asked to recall the child as advised by national guidelines (every 3 months if continue to be high risk). At the end of the second year we will contact the GDP to request details of appointments attended and failed to attend; any preventive advice or treatment. We may also access electronic payment records to obtain this information.

Group 2 (control group): Placebo Control Intervention
The review appointment will be conducted by an Additional Skills Dental Nurse (ASDN) or dental therapist trained by the research team. The session will be tape recorded and start with a review of the dental extraction (if it has occurred); the discussion will then move onto future dental development. This control intervention has the same structure as the DR-BNI but the delivery mode is educational rather than negotiated goal setting. The ASDN will provide information and discuss subsequent dental development that occurs between 6 and 14 years when most of the permanent teeth will erupt. The information will be structured around concepts of growing up, shedding and growing new teeth; descriptions and illustrations of the eruption of permanent teeth with primary precursors followed by eruption of molars with no precursors. No discussion on prevention will occur.

All families (both DR-BNI and Placebo Control) will receive the same summary leaflet on dental development information to take home. At the end of the review appointment, participants in the control group will be advised to continue with their child's GDP arrangements as usual.

The participant's GDP will have been informed of their patients' involvement in the research. At the end of the first and second year we will contact the GDP to request details of appointments attended and failed to attend; any preventive advice or treatment. We may also access electronic payment records to obtain this information.

Previous interventions:
Parents/guardians of children, between 5 and 7 years, who are booked for an extraction for tooth decay, will be invited to take part. They will be randomly allocated to either, usual follow-up care or to the new dental nurse-led service.

Dental RECUR: Group 1 (test group)
Participants will attend a review appointment (MI intervention) 2-6 weeks post extraction. The parents/guardians of test group patients will have an appointment scheduled for the review before leaving the secondary care centre on the day of their extraction appointment. Participants will be given an appointment card and will be sent a text reminder the day before the review. The review appointment will be conducted by an Additional Skills Dental Nurse (ASDN) or dental therapist trained by the research team in motivational interviewing.

The session will be tape recorded and start with a review of the dental extraction; the discussion will then move onto future dental care. The session will establish parents' stage of change and allow a tailored programme to be planned in relation to enhancing parental efficacy in three key child dental health-related behaviours: establishing twice daily toothbrushing with fluoridated toothpaste, particularly night time; reducing frequency of sugary foods and drinks; attending for preventive rather than symptomatic dental care. At the end of the appointment the ASDN will assist the participant to make the first of their quarterly recall appointments with their General Dental Practitioner (GDP). If the participant does not have a GDP the ASDN will assist the participant in finding a local practice and making their first appointment if appropriate. The review appointment will take approximately 1 hour.

The participant's GDP will have been informed of their patients' involvement in the research and advice regarding frequency of recall visits and preventive care (as advised by the Department of Health [DH] in Delivering Better Oral Health [a guidance manual on recommended prevention provided to each GDP by the DH]). This guidance recommends that high caries risk child patients are recalled at 3, 6, 9 and 12 months post extraction. The first recall appointment will be arranged during the ASDN-led review (above); all subsequent quarterly recall appointments will be organised between the participant and their GDP. It is anticipated that the GDP will have a text message service to remind parents of their appointment prior to each recall. We will ask the participant's GDP to complete a CRF and send it back to the co-ordinating centre each time the participant attends their dental practice in the first year.

There will be no active intervention in the second year and the practice will be asked to recall the child as advised by national guidelines (every 3 months if continue to be high risk). At the end of the second year we will contact the GDP to request details of appointments attended and failed to attend; any preventive advice or treatment. We may also access electronic payment records to obtain this information.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Dental caries experience after 2 years,; Timepoint(s): 2 years post extraction

Key secondary outcome(s))
Current secondary outcome measures as of 22/10/2015:
1. Parental readiness to change and beliefs about caring for their children's teeth. Measured by the modified Contemplation Ladder
2. Parental self-efficacy in relation to the implementation of dental-health related behaviours for the study children. Measured by the Child Oral Health Behaviours Questionnaire and Parenting Self Efficacy Scale
3. Oral cleanliness by plaque assessment of anterior teeth at dental examinations
4. Use of dental services; child oral health behaviours including dietary behaviours. Measured by the Child Oral Health Behaviours Questionnaire
5. NHS costs will be measured: from a public sector, multi-agency perspective, we will:
5.1. Fully cost the community-based DR-BNI and prevention in dental practice programme (as compared with costs of usual dental care)
5.2. Record study participant dental service use, primary and secondary care health service use, social care and special educational service use (using aCSRI, costed using national unit costs)
5.3. Conduct a primary cost-effectiveness analysis (using dental caries rates as our measure of effectiveness)
5.4. Conduct a secondary cost-consequences study relating costs to a range of consequences spanning measures of: dental decay in participating child, regular dental attendance, parent participation in better oral health behaviours (e.g., sugar-free bedtime routine) and school attendance, and where appropriate, potential child neglect

Previous secondary outcome measures:
1. Parental beliefs about caring for their children's teeth. Measured by The Readiness Assessment of Parent's Concerning Infant Dental Decay (RAPIDD)
2. Parental self-efficacy in relation to the implementation of dental-health related behaviours for the study children. Measured by the Child Oral Health Behaviours Questionnaire
3. NHS costs will be measured: from a public sector, multi-agency perspective, we will:
3.1. Fully cost the community-based motivational interviewing and health education in dental practice programme (as compared with costs of usual dental care)
3.2. Record study participant dental service use, primary and secondary care health service use, social care and special educational service use (using an interviewer-administered CSRI, costed using national unit costs)
3.3. Conduct a primary cost-effectiveness analysis (using dental caries rates as our measure of effectiveness)
3.4. Conduct a secondary cost-consequences study relating costs to a range of consequences spanning measures of: dental decay in participating child, regular dental attendance, parent participation in better oral health behaviours (e.g., sugar-free bedtime routine) and school attendance, and where appropriate, potential child neglect.

Completion date
01/12/2018

Eligibility

Key inclusion criteria

1. The population of children defined as eligible to participate in this study will be any child, male and female, aged 5 and 7 years (past their 5th birthday and not attained their 8th birthday) who is scheduled to have one or more primary teeth extracted for dental caries under general anaesthesia, relative analgesia (inhalation sedation) or local anaesthetic at a secondary care centre
2. The parent/ guardian will have consented to join the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
241

Key exclusion criteria
1. Any child who is scheduled to have all of their first permanent molar teeth extracted
2. Children who are currently participating in any other trial or have done so in the previous 3 months
3. Any child who is severely disabled

Date of first enrolment
01/11/2013

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal Hospitals NHS Trust
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Salford Royal NHS Foundation Trust (UK)

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility; Grant Codes: PB-PG-0610-22310

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	17/01/2020	Yes	No
Results article	Cost-effectiveness analysis	17/03/2022	18/03/2022	Yes	No
Protocol article	protocol	04/11/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes