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An oral health intervention delivered by dental teams to parents of young children ("Strong Teeth"): feasibility protocol

Submission date
09/07/2019

Recruitment status
No longer recruiting

Registration date
24/07/2019

Overall study status
Completed

Last Edited
19/05/2021

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dental teams need to be able to help parents to adopt appropriate home-based oral health behaviours, to optimise the benefits of dental attendance for young children (0-5 years old). Dental professionals, the local community and researchers at the University of Leeds have collaborated with Oral-B to develop "Strong Teeth", an oral health promotion intervention to be delivered in the one-to-one setting of general dental practice. This early phase study will explore the acceptability of the intervention to parents and the dental team trained in the intervention, as well as explore changes in oral health behaviour, how the intervention works, a the suitability of providing children aged 3-5 years old with an Oral-B electric toothbrush.

Who can participate?
In areas of Yorkshire (Bradford, Leeds and the surrounding areas) where children are at high risk of dental caries, 20 parents of children aged 0-2 years old and 20 parents of children aged 3-5 years old who are about to attend the dentist for their child's regular check-up, will be recruited to the study from 4-8 different dental practices.

What does the study involve?
In the home setting, consent and baseline (starting point) oral health behaviour data will be collected. A researcher will ask validated questions to parents about their oral health behaviours, including child toothbrushing and dietary behaviours. Three different measures of toothbrushing will be collected and compared with parental self-reports. The parent/child will then attend their dental visit and receive the "Strong Teeth" intervention, delivered by the dental team. At 2 weeks and 2-3 months following the "Strong Teeth" intervention, further self-reported and measures of oral health behaviours will be collected in the parent/child's home. This data will be supplemented with qualitative interviews with parents (2-3 months following the intervention) and with dental team members (following delivery of the intervention).

What are the possible benefits and risks of participating?
Dental professionals will be provided with training on how to deliver the "Strong Teeth" intervention that will contribute to the quality of their professional practice. In addition, during

the interview/focus group, dental team members will discuss their professional practices and experiences and this will enable them to exchange knowledge and learn from each other. Parents and children will receive oral health advice from a trained dental professional on how to care for children's oral health. Parents of children aged 3-5 years will also receive a free electric Oral-B toothbrush. It is not anticipated that any distress will be caused to participants. However, the research team have been appropriately trained and procedures are in place should any issues arise.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
September 2018 to September 2019

Who is funding the study?
Procter and Gamble

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
248833

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2; IRAS: 248833

Study information

Scientific Title
“Strong Teeth” – a study protocol for an early-phase feasibility trial of a complex oral health intervention delivered by dental teams to parents of young children

Study objectives
Feasibilty study primary aim:
To undertake an early-phase feasibility trial of the “Strong Teeth” intervention delivered by dental teams to parents of children aged 0-5 years old.

Feasibilty study primary objectives:
Using a mixed-methods approach (including self-report questionnaires, dental examinations, filming the toothbrushing interaction between parent and child, and qualitative interviews):
1. To explore with NHS dental teams, the acceptability and feasibility of delivering the “Strong Teeth” intervention to parents of children aged 0-5 years old
2. To review study findings against progression criteria (see Table 1) and determine whether progression to a definitive trial is appropriate

Feasibility study secondary objectives:
1. To explore with parents of children aged 0-5 years old the acceptability of the “Strong Teeth” intervention
2. To study the mechanisms of action for the “Strong Teeth” intervention
3. To correlate different proxy objective measures of toothbrushing with parental self-reports of parental supervised toothbrushing (PSB, i.e., the parent actively brushing their childs teeth)
4. To describe the changes in dietary behaviour and PSB as a result of the “Strong Teeth” intervention in children aged 0-5 years old
5. To examine the impact of providing children aged 3-5 years old with an Oral-B electric rechargeable toothbrush, with respect to acceptability and toothbrushing behaviours

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/09/2018, Yorkshire & The Humber – Leeds East Research Ethics Committee (Tel: +44 (0)207 1048 088, +44 (0)207 104 8026; Email: nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 18/YH/0326; NHS Health Research Authority (Skipton House, 80 London Road, London SE1 6LH; Email: hra.approval@nhs.net), IRAS: 248833

Study design
Observational mixed methods

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dental caries (tooth decay)

Interventions
The “Strong Teeth” intervention serves to provide a structure and hierarchy to the behaviour change conversation between dental practitioners and parents of children aged 0 - 5 years old. It is divided into three sections: (1) Check motivation—Why is oral health important? (2) Check brushing technique—How to brush; and (3) Identifying other barriers to oral health (e.g., healthy eating, influence of family and friends, managing the child’s behaviour to enable brushing, remembering to brush)—How to overcome these barriers. A variety of paper and digital resources for both dental professionals and parents are available to support the conversation.

In areas of Yorkshire (Bradford, Leeds and the surrounding areas) where children are at high risk of dental caries, 20 parents of children aged 0-2 years old and 20 parents of children aged 3-5 years old who are about to attend the dentist for their child’s regular check-up, will be recruited to the study. We will recruit parents and children attending 4-8 different dental practices.

In the home setting, consent and baseline (starting point) oral health behaviour data will be collected. A researcher will ask validated questions to parents about their oral health behaviours, including child toothbrushing and dietary behaviours. Three different measures of toothbrushing will be collected and compared with parental self-reports. The parent/child will then attend their dental visit and receive the "Strong Teeth" intervention, delivered by the dental team. At 2 weeks and 2-3 months following the "Strong Teeth" intervention, further self-reported and measures of oral health behaviours will be collected in the parent/child’s home. This data will be supplemented with qualitative interviews with parents (2-3 months following the intervention) and with dental team members (following delivery of the intervention).

Intervention Type
Behavioural

Primary outcome(s)
The acceptability and feasibility of the intervention for dental practitioners and parents will be assessed via the completion of:
1. A semi-structured diary for dental practitioners to be completed after that delivery of each interventional session
2. Interviews/focus groups with dental practitioners and parents

Key secondary outcome(s))
At baseline, and 2 weeks and 3 months post intervention the following measures will be taken:
1. Questionnaire assessing children's toothbrushing and dietary habits
2. Three proxy objective measures of parental supervised toothbrushing:
2.1. Children’s pre-brushing plaque levels
2.2. Duration of toothbrushing and parent-child interaction during toothbrushing - filmed and independently coded
2.3. Toothbrushing activity measured via the Magic Timer App
3. Dental examination assessing ginigivitis and number of teeth present, missing and decayed

Completion date

15/09/2019

Eligibility

Key inclusion criteria
1. Children 0-5 years old about to visit their general dental practice for a dental check-up
2. Children attending a general dental practice where the dental team is trained to deliver the "Strong Teeth" intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
5 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Only one sibling can be recruited per household
2. A parent must be present at the baseline home visit to ensure valid consent

Date of first enrolment
10/10/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Leeds
School of Dentistry
Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble

Alternative Name(s)
Procter & Gamble, PandG, The Procter & Gamble Company, P and G, Procter & Gamble Company, P&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/03/2021	22/03/2021	Yes	No
Results article		17/05/2021	19/05/2021	Yes	No
Protocol article	protocol	13/08/2019	16/08/2019	Yes	No
HRA research summary			28/06/2023	No	No