ISRCTN21461006 https://doi.org/10.1186/ISRCTN21461006

BBaRTS Children's Healthy Teeth Programme

Submission date 16/09/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/09/2015	**Overall study status** Completed	
Last Edited 11/12/2018	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
A series of eight storybooks has been developed by a health psychologist, public health dentist, science educator, children's author and illustrators with guidance from the Department for Education (England). The storybooks are designed to encourage twice daily toothbrushing with fluoride toothpaste and discourage eating sugary snacks, especially at bedtime. The aim of this study is to find out whether children’s dental health can be improved using these storybooks.

Who can participate?
Children aged 5-7 at 60 primary schools in England and Scotland whose headteachers have agreed to participate in the study.

What does the study involve?
Participating schools are randomly allocated to one of three groups. Children in group 1 schools receive the storybooks containing the dental health messages. Children in group 2 schools receive storybooks with exactly the same illustrations, characters and story but without the dental health messages. Children in group 3 schools receive the storybooks containing the dental health messages, undertake supervised toothbrushing at school, and receive a supply of toothbrushes and toothpaste to use at home. All children in the study will have a dental examination annually and parents will be asked to complete questionnaires at the start of the study and after 1 and 2 years. A subset of children and families are invited to join a study of the child’s diet and saliva composition at the start of the study and at the final assessment 2 years later.

What are the possible benefits and risks of participating?
All children whose parents give permission for them to take part will be given 8 bright and colourful story books to take home and keep. Risks to all participants could include inconvenience due to time taken to complete the questionnaire (up to 30 minutes on three occasions).

Where is the study run from?
60 primary schools across England and Scotland (UK).

When is the study starting and how long is it expected to run for?
June 2013 to December 2017.

Who is funding the study?
Queen Mary University of London (UK).

Who is the main contact?
Louise Robinson
louise.robinson@srft.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Ms Cynthia Pine

Contact details
Institute of Dentistry
Barts and The London School of Medicine and Dentistry
Turner Street
London
United Kingdom
E1 2AD

Type(s)
Public

Contact name
Ms Louise Robinson

Contact details
Institute of Dentistry
Barts and The London School of Medicine and Dentistry
Turner Street
London
United Kingdom
E1 2AD
+44 (0)207 882 8636
l.robinson@qmul.ac.uk

Additional identifiers

Protocol serial number
QMREC2013/43

Study information

Scientific Title
A cluster randomised controlled trial to prevent dental caries in primary school children: The BBaRTS Healthy Teeth Behaviour Change Programme

Acronym
BBaRTS

Study objectives
The primary aim of this research is to determine whether children's dental health can be improved by increasing parental self-efficacy using a storybook approach for two child behaviours: toothbrushing and sugars snacking. Specifically, with the following objective:

Objective:
To determine whether an intervention (Test 1) designed to increase parental self-efficacy using a storybook approach with embedded Behaviour Change Techniques (BCTs) for two child behaviours: toothbrushing with fluoride toothpaste and reducing consumption of free sugars, especially at bedtime, can improve child oral health compared to:
1. An exactly similar intervention without embedded health messages and BCTs (Control)
2. The intervention (Test 1) supplemented with home supply of fluoride toothpaste and supervised toothbrushing on schooldays (Test 2).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen Mary University Ethics Committee, 21/08/2013, ref: QMREC2013/43

Primary study design
Interventional

Study design
Three-arm multicentre cluster randomised controlled trial with blinded outcome assessment

Study type(s)
Prevention

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

Interventions
A series of 8 story books have been developed by a health psychologist, public health dentist, science educator, children's author and illustrators with guidance from the Department for Education (England). The books are given out each school term over two years.

Participants are children (estimated 2000 – 2600) aged 5-7 years and their families from 60 Primary Schools in England and Scotland. Schools are randomized into three groups:
Group 1 (test 1) will receive 8 story books (the test books) containing the intervention messages
Group 2 (control) will receive 8 story books with exactly the same illustrations, characters and story but without the intervention messages
Group 3 (test 2) will receive the 8 test books and supervised toothbrushing at school and a supply of toothbrushes and toothpaste to use at home

Intervention Type
Behavioural

Primary outcome(s)
Dental caries experience in permanent teeth at age 7 years, measured by a simple visual dental examinations conducted in the child's school at baseline, after one year and after two years. The examinations will be conducted by independent dental examiners, trained in standardised dental epidemiological survey techniques and blinded to the group allocation of the school. Dental caries experience on any surface in either dentition will be recorded. All children will be examined using sterilised or single use mouth mirrors, CPITN probes, a standardized halogen lamp (2,000 lux) and cotton wool rolls as needed.

Key secondary outcome(s)
1. Oral cleanliness, measured by plaque assessment on the buccal surfaces of upper anterior teeth at the dental examinations
2. Oral health behaviours
3. Family satisfaction
4. Early Child Oral Health Impact
5. Reading Intensity

Parents/guardians of children will be asked to complete a questionnaire pack at baseline, one year and two years post enrollment.

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Children aged 5-7 at primary schools in England and Scotland whose headteachers have agreed to participate in the study
3. Parent/legal guardian completed informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
7 Years

Sex
All

Key exclusion criteria

1. No parent/guardian consent obtained
2. Schools that have existing toothbrushing programmes or fluoride varnish schemes

Date of first enrolment
07/09/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

Study participating centre
60 primary schools across England and Scotland
United Kingdom
-

Sponsor information

Organisation
Queen Mary University of London (UK)

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
University/education

Funder Name
Queen Mary University of London, supported by an unrestricted grant from GSK

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/02/2016		Yes	No