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Salford Bright Smiles Baby Study

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/10/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/03/2018	**Condition category** Oral Health	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8483

Study information

Scientific Title

A comparison of community based preventive services to improve child dental health: a single centre randomised interventional prevention trial

Study objectives
The primary hypotheses are that:
1. There is no difference in the proportions of children with dental caries at age 3 years between test group 1 (behavioural intervention) and the control group
2. There is no difference in the proportions of children with dental caries at 3 years between test group 2 (fluoride varnishing) and the control group

The test interventions will be four semi-annual applications of a fluoride varnish from approximately age 12 months to 30 months, or a ten session group-based behavioural intervention targeting two dental health-related behaviours: establishing twice daily tooth-brushing and a sugar-free bedtime routine, compared to a new standard dental service offered to families with babies aged 9 - 12 months.

There will be no specific criteria for excluding any child in the trial except with reference to the provision of fluoride varnish which is contraindicated with previous hospitalisation because of hypersensitivity reactions including asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 8 REC Greater Manchester East, 26/03/2010, ref: 10/H1013/8

Study design
Single-centre randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
1. A group-based behavioural intervention targeting two dental health related behaviours: Establishing twice daily tooth-brushing and a sugar-free bedtime routine, The behavioural

interventions will be delivered as group sessions of 8 - 10 parents facilitated by a healthcare professional and an 'expert parent'. The intervention will be delivered in blocks of two or three weekly sessions over 10 to 12 sessions as the child's age increases from 12 to 30 months.
2. A clinical intervention of semi annual applications of fluoride varnish (up to 0.4 ml of 0.9% difluorosilane in a polyurethane varnish base). Four doses of topically applied fluoride varnish will be delivered to the deciduous teeth of infants commencing at a minimum age of 12 months and repeated at approximately 18, 24 and 30 months.

Duration of both interventions: 18 months
Follow up length: 24 months
Study entry: single randomisation only

Intervention Type
Mixed

Primary outcome measure
Improvement in dental health, measured by the standard dental index (d1mft) number of decayed, extracted and filled teeth. Measured at age 2 years and age 3 years (12 and 24 months from enrolment respectively).

Secondary outcome measures
Enhancement of parental efficacy to undertake two key dental health-related behaviours, measured twice daily at baseline, age 2 and age 3 (enrolment,12 and 24 months).

Overall study start date
30/04/2010

Completion date
30/10/2013

Eligibility

Key inclusion criteria
1. Parents or principal carers of a child between 8 and 12 months of age at recruitment
2. Residing in the City of Salford
3. Able to read and understand the study literature with/out a translator/interpreter and provide written informed consent

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned sample size: 732; UK sample size: 732

Key exclusion criteria
There will be no specific criteria for excluding any child in the trial except with reference to the provision of fluoride varnish which is contra-indicated with previous hospitalisation because of hypersensitivity reactions including asthma.

Date of first enrolment
30/04/2010

Date of final enrolment
30/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Salford
Salford
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Sponsor information

Organisation
University of Salford (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.salford.ac.uk

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration