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Salford Bright Smiles Baby Study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)

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).

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

Study participating centre
University of Salford
Salford
United Kingdom
M6 6PU

Sponsor information

Organisation
University of Salford (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration