

Salford Bright Smiles Baby Study

Submission date 21/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/03/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes