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Salford Bright Smiles Baby Study

Submission date 21/10/2010	Recruitment status No longer recruiting	
Registration date 21/10/2010	Overall study status Completed	
Last Edited 29/03/2018	Condition category Oral Health	

- Prospectively registered
-] Protocol
- Statistical analysis plan
- Results
-] 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 toothbrushing 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 United Kingdom M6 6PU

Sponsor information

Organisation University of Salford (UK)

Sponsor details

c/o Tony Warne Professor in Mental Health Care Associate Dean (Research) Head of School School of Nursing & Midwifery Mary Seacole Building Salford England United Kingdom M6 6PU +44 (0)161 295 2779 a.r.warne@salford.ac.uk

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