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A clinical trial of the effectiveness of a dental caries prevention program for young children

Submission date 16/11/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/11/2005	**Overall study status** Completed	
Last Edited 10/12/2007	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-63155

Study information

Scientific Title

Study objectives
The hypotheses are that at study completion:
1. Children of caregivers randomised to the intervention group will have a mean number of decayed, missing or filled tooth surfaces (dmfs) one less than that of children whose caregivers were randomised to the control group
2. The proportion of children of caregivers in the intervention group who are caries free will be 20% more than the proportion of children caries free in the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the McGill Faculty of Medicine Institutional Review Board on the 6th January 2003.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Early childhood caries

Interventions
The test intervention is an educational one delivered by dental hygienists to parents of infants when the latter are 6, 12, 18 and 24 months old. Each of the four sessions lasts approximately 15 minutes.

The control group receive no intervention i.e. 'normal care'.

Trial details received: 12 September 2005

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Number of decayed missing and filled tooth surfaces 24 months following recruitment.

Secondary outcome measures
1. Percentage of children without dental caries
2. Parent caries-related knowledge
3. Parent caries-related behaviour
4. Oral health-related impacts/quality of life
5. Child weight
6. Financial costs

Overall study start date
01/09/2003

Completion date
31/05/2006

Eligibility

Key inclusion criteria
1. Caregivers (parents) who have a child of five to seven months, either sex (inclusive), with whom they are attending the vaccination clinics of the study community health centre recruitment sites (CLSCs) and who live with that child for 50% or more of the time will be asked to participate
2. The subjects included are parent/infant dyads

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Months

Upper age limit
7 Months

Sex
Both

Target number of participants
821

Key exclusion criteria

Dyads will be excluded if parents are unable to understand the consent form and self-complete questionnaires for linguistic reasons

Date of first enrolment
01/09/2003

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
Canada

Study participating centre
Faculty of Dentistry
Montreal
Canada
H3A 2B2

Sponsor information

Organisation
McGill University (Canada)

Sponsor details
3640 University St.
Montreal
Canada
H3A 2B2

Sponsor type
Not defined

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-63155)

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