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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 16/11/2005 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 16/11/2005 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 10/12/2007 | Oral Health | [ ] 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

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
Number of decayed missing and filled tooth surfaces 24 months following recruitment.

## Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
5 months

### Upper age limit
7 months

### Sex
All

### 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
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# Sponsor information

**Organisation**
McGill University (Canada)

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration