

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/12/2007	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

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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

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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