ISRCTN26422175 https://doi.org/10.1186/ISRCTN26422175

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