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Dental caries prevention program for Cree mothers and infants

Submission date 29/06/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2004	**Overall study status** Completed	
Last Edited 04/01/2013	**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-67817

Study information

Scientific Title
A clinical trial of the effectiveness of a dental caries prevention program for Cree mothers and their infants

Acronym
CreeC

Study objectives
Primary question:
Is there any difference in the dental health status of young Cree children whose mothers have participated in a client-centred, one-on-one, preventive counseling intervention, motivational interviewing (MI), and children whose mothers received oral health information in the form of an educational pamphlet? This question will be answered by testing the hypothesis that the prevalence of caries in 30 month old children will be lower in the experimental communities than in the control communities.

Secondary questions:
Are Cree mothers knowledge and beliefs about child dental health issues, their dental health practices, and child feeding and comforting practices altered by participation in a series of motivational interviewing (MI) interventions? This question will be answered by testing the null hypothesis that there will be no difference between the two groups of mothers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of British Columbia (UBC) Behavioural Research Ethics Board (ref: Certificate B04-0295) - this is re-approved annually.

Study design
Randomised controlled 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 below to request a patient information sheet

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

Interventions
Primary intervention is behavioural: motivational interviewing (MI)
Experimental group: The first MI session will occur during pregnancy at time of enrolment. Mothers will participate in at least five more MI sessions that will correspond with well-child immunisation visits between two and 24 months of age. Fluoride varnish will be offered at the 12, 18 and 24 month visits.

Control group: Mothers will receive a pamphlet. Fluoride varnish will be available at local dental clinics.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The prevalence of caries, or percentage of 30 month old children with decayed, extracted and filled surfaces (DEFS) more than zero, in each community will be determined. A childs experience of caries will be determined by recording the DEFS, or number of decayed, extracted or filled primary tooth surfaces.

Secondary outcome measures
Data on dental health knowledge, oral home care practices, child-feeding and comforting practices will be collected at 30 months and compared between test and control communities. In addition, data on "caries-related health impacts", for example, history of pain, food avoidance or poor sleeping as a result of dental pain, and dental treatment received as a result of dental caries will be compared.

Overall study start date
01/04/2004

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. 309 Cree mother-child pairs in Eeyou Istchee (Cree territory of northern Quebec)
2. Mothers aged 18 - 49 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
309

Key exclusion criteria
Any pregnant women or woman with a newborn who knows that she will be imminently moving out of the Cree territory.

Date of first enrolment
01/04/2004

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Canada

Study participating centre
2199 Wesbrook Mall
Vancouver, BC
Canada
V6T 1Z3

Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details
Room 97
160 Elgin Street
Address locator: 4809A
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info@cihr-irsc.gc.ca

Sponsor type
Research organisation

Website
http://www.cihr-irsc.gc.ca/

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-67817)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/05/2010		Yes	No
Results article	results	01/11/2012		Yes	No